

EXHIBIT 2

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
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Monday, May 13, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, held at Weitz & Luxenburg PC, 3011
West Grand Avenue, Suite 2150, Detroit,
Michigan, commencing at 9:20 a.m., on the
above date, before Michael E. Miller, Fellow
of the Academy of Professional Reporters,
Registered Diplomate Reporter, Certified
Realtime Reporter and Notary Public.

GOLKOW LITIGATION SERVICES
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deps@golkow.com

1 Q. Have you ever served as an
2 expert witness on a consulting basis before?

3 A. No, sir, I have never served as
4 an expert in the capacity of a consultant.

5 Q. Okay. Have you ever written
6 any articles that were published?

7 A. No, sir.

8 Q. Have you ever written anything
9 of any kind that was published?

10 A. As a police officer, I wrote an
11 article at the request of the Detroit News.
12 It was in regards to the effectiveness of the
13 DARE program.

14 Q. Okay. So you wrote something
15 for the Detroit -- is it the Detroit News?

16 A. Detroit News, it's the
17 publication.

18 Q. Did that used to be the Detroit
19 Free Press or is that a different paper?

20 A. Different paper. Still two
21 papers in Detroit.

22 Q. Okay. Was that like an op-ed,
23 like an editorial kind of thing?

24 A. Sure. They published two, I
25 guess, opinions, a pro and a con opinion.

1 Mine was the pro opinion of DARE, and there
2 was a side-by-side con opinion of the
3 effectiveness of that program.

4 Q. Okay. So you wrote that. Is
5 there anything else you've ever written
6 that's been published?

7 A. Not that I'm aware of, not that
8 I gave any authorization for, no, sir.

9 Q. Okay. Have you -- and this is
10 pretty obvious, but you're not an attorney;
11 is that correct?

12 A. Not an attorney, no, sir.

13 Q. So in giving your opinions
14 today, you're not trying to give legal
15 opinions; is that right?

16 A. Well, the opinion I'm trying to
17 give is based on my training and experience
18 and my knowledge of the law and the
19 regulations that are required to be adhered
20 to by the companies. I'm not publishing a
21 legal opinion as an attorney.

22 Q. Well, what I'm asking you is
23 whether you -- are you offering today or in
24 your report a legal -- a legal conclusion?

25 A. I think, yes, I am.

1 Q. Okay. Let me ask you a little
2 about the work you've done in connection with
3 this report.

4 First of all, the report is 180
5 pages, I believe.

6 A. It is, sir.

7 Q. Did you write it?

8 A. Yes, sir.

9 Q. Okay. You wrote it yourself or
10 did you write it with help?

11 A. I wrote it with help.

12 Q. Okay. How much time did you
13 spend preparing your report?

14 A. Well, I didn't keep track if
15 you're going to ask me the exact hours, but I
16 would say a considerable amount of time. It
17 pretty much consumed me.

18 Q. When did you start working on
19 the report?

20 A. Well, probably in the fall of
21 2018, I started having discussions about the
22 type of documents and records that I would
23 need, some of the topics in potential
24 depositions, questions I would need to
25 answer. So I started to give the framework

1 So within those families,
2 there's -- my experience in doing these cases
3 is there's generally a hierarchy of drugs
4 where some drugs are ordered more often than
5 others. They're just generally prescribed
6 more.

7 So during the course of when a
8 potential diversion would occur, there could
9 be one strength of drug which actually
10 occurred -- which really impacted what
11 happened in America -- the oxycodone 30
12 product became a highly abused product. So
13 companies should or would want to monitor
14 within that drug family if there was a change
15 in pattern where one drug started to get
16 ordered in a much greater amount than the
17 other drugs.

18 Along those same lines, another
19 pattern is how companies order drugs.
20 Typically in the old days they used DEA
21 Form 222s. That's a paper form with ten
22 lines. Some companies generally order drugs
23 in the same manner.

24 I've reviewed countless number
25 of forms, and as you go through the forms day

1 by day, you'll see patterns on how drugs are
2 ordered, certain groups together. In the
3 cases I've worked, when that pattern changes,
4 so an easy one would be all of a sudden you
5 see an order form with ten lines and all ten
6 lines have oxycodone 30. If a company would
7 start to change a pattern of orders like
8 that, that would be an easy one.

9 Q. Is it also possible that
10 patterns or size or frequency can change
11 suddenly based on changed circumstances in a
12 particular community?

13 A. Sure, anything is possible.

14 Q. Well, I don't just mean
15 anything is possible. I mean, yes, anything
16 is possible, but I'd like to be a little more
17 specific.

18 A. Okay.

19 Q. Let's say -- let's say a
20 hospital opens up in an area. Would that
21 change patterns and could it change ordering
22 patterns and size of orders and frequency of
23 orders?

24 A. Well, I think that obviously
25 has a possibility to cause some change. I'm

1 not sure that it would change the pattern.
2 It may change the amounts or the types. So
3 another -- as was one of my examples, the
4 types could change.

5 Anytime a business model
6 changes or a new contract -- a better
7 example, if I could give you a better
8 example.

9 Q. Sure.

10 A. Is a pharmacy could enter into
11 a contract with a long-term care facility,
12 and if they didn't provide guidance or
13 information to their distributor, they could
14 just start ordering a controlled substance
15 that would be out of the norm of something
16 they ever ordered before.

17 That's kind of the essence of
18 the suspicious order system because you would
19 hope the system would trigger to stop that
20 order. Then it requires some due diligence
21 where a company would actually call and they
22 would learn about that contract. And then
23 subsequent to that, the distributor or the
24 person making the sale would probably confirm
25 that that actual contract occurred and that

1 business relationship occurred.

2 So...

3 Q. So patterns can change?

4 A. Sure.

5 Q. Size can -- you know, unusual
6 size can change. Frequency can change
7 depending on the circumstances that occur in
8 a particular community, right?

9 A. I've learned in my experience
10 that the ordering and distribution of drugs
11 is not static. It's heavily patterned,
12 especially the more the customers, the more
13 the established pattern, sizes and frequency.
14 But new drugs could be introduced.

15 There's a lot of reasons why it
16 could change. And that's not a bad thing,
17 but those are the things that would trigger
18 your system to stop an order and then you to
19 evaluate it to make sure that -- not you
20 personally, but so that it's evaluated, and
21 then there's no chance of diversion.

22 Q. So while that investigation is
23 going on, you're saying that those drugs
24 should not be shipped to a place where let's
25 say there's a new -- a new long-term facility

1 Do you agree with that
2 statement that Mr. Rannazzisi made?

3 MR. FULLER: Form, outside of
4 his scope.

5 A. Can you read it one more time
6 for me?

7 BY MR. NICHOLAS:

8 Q. Yes.

9 DEA recognizes that the
10 overwhelming majority of registered
11 distributors act lawfully and take
12 appropriate measures to prevent diversion.

13 A. Well, based on my work on this
14 matter and my review of records and systems,
15 which I didn't have any previous knowledge of
16 previous to when I did that, I would probably
17 disagree with that statement by
18 Mr. Rannazzisi, in looking at the historic
19 failures by the companies to be in compliance
20 with the suspicious order situation -- or
21 regulation and just a general broad
22 maintenance of effective controls to prevent
23 diversion.

24 MR. NICHOLAS: It's been --
25 well, let's take a short break. We'll

1 go another 45 minutes after that and
2 have lunch, if that's okay.

3 THE VIDEOGRAPHER: Going off
4 the record, 11:34 a.m.

5 (Recess taken, 11:34 a.m. to
6 11:45 a.m.)

7 THE VIDEOGRAPHER: We're back
8 on the record at 11:45 a.m.

9 BY MR. NICHOLAS:

10 Q. The DEA requires the retention
11 of records to be for at least two years; is
12 that correct?

13 MR. FULLER: Form.

14 BY MR. NICHOLAS:

15 Q. By policy?

16 A. Well, by regulation --

17 Q. By regulation.

18 A. -- the requirement is -- and
19 that two-year applies to required records.
20 So within the CFR, there are certain records,
21 examples would be biannual inventories, order
22 forms. Any of the records that are in the
23 records section of the CFR have a two-year
24 retention.

25 And there's a carve-out that if

1 a state has a longer retention period, that
2 the registrant could be subjected to that,
3 but that two years only applies to those
4 certain records that are cited in the CFR.

5 Q. So -- but the carveout that
6 you're talking about doesn't apply to
7 suspicious order reports, right? That's
8 within the two -- that's subject to the
9 two-year regulation?

10 MR. FULLER: Form.

11 A. No. The suspicious order
12 reports aren't part of the two-year
13 retention.

14 BY MR. NICHOLAS:

15 Q. They don't have to be retained
16 at all?

17 A. Well, under my opinion, it
18 would be they would be retained forever.

19 Q. Right, but, I mean, the
20 regulation doesn't require -- I understand
21 that might be your opinion, but is there any
22 regulation that says they have to be retained
23 for any length of time?

24 A. I would say the maintenance of
25 effective controls to prevent diversion would

1 be applicable to say that they should retain
2 the suspicious order reports or any due
3 diligence related to them.

4 Q. There are specific sections --
5 there are specific regulations that address
6 records retention, correct?

7 A. Yes, sir.

8 Q. And those --

9 MR. FULLER: Form.

10 BY MR. NICHOLAS:

11 Q. -- regulations identify the
12 categories of records that have to be kept
13 and for how long, correct?

14 MR. FULLER: Form.

15 A. The CFR does address that, but
16 those are the required records. For example,
17 there are some records that registrants keep
18 in the course of their business that aren't a
19 required record. So just so we're on the
20 same understanding as to -- the two-year
21 retention is only under those required
22 records; dispensing records for a dispensing
23 doctor, two-year retention; biannual
24 inventories, order forms, those are all part
25 of the required records.

1 BY MR. NICHOLAS:

2 Q. So the things we're talking
3 about now, suspicious order reports or due
4 diligence documents, are not part of the
5 kinds of records that are required to be
6 retained under the CFR and the regulations?

7 A. Well --

8 Q. That's a yes or a no.

9 MR. FULLER: Object to form.
10 He's already testified they were.

11 MR. NICHOLAS: That's not what
12 he said.

13 Go ahead.

14 THE WITNESS: So could you
15 restate the question? I'm sorry.

16 BY MR. NICHOLAS:

17 Q. Does the CFR or its regulations
18 require in writing and as identified
19 suspicious order reports?

20 MR. FULLER: Form.

21 MR. NICHOLAS: I'll ask it
22 again. It was a crappy question.

23 BY MR. NICHOLAS:

24 Q. Does the CFR identify
25 suspicious order reports as among the

1 documents that have to be retained for at
2 least two years?

3 A. I would say yes, under the
4 maintenance of effective controls, but I
5 think there's not a lot of clarity on whether
6 that is essentially a required record.

7 Q. Does the CFR identify due
8 diligence documents as documents that are
9 required to be retained for at least two
10 years?

11 A. I'm going to respond the same:
12 Under maintenance of effective controls, I
13 think that requirement requires the retention
14 of due diligence records. The CFR doesn't
15 speak specifically to a due diligence record,
16 but that would be a record that would be
17 maintained within the requirement of that
18 regulation.

19 Q. For at least two years?

20 A. Again, my opinion, they should
21 be kept permanently.

22 Q. No, I'm not asking about your
23 opinion. I'm asking under -- what the
24 requirement is under the law as you
25 understand it.

1 A. Under the regulation as I
2 understand it --

3 Q. Yeah.

4 A. -- it doesn't speak
5 specifically to due diligence records. So
6 I -- a two-year retention -- if a registrant
7 was to review the CFR, there's no mention of
8 a due diligence record, so I would say it's
9 not two years.

10 But again, I'd just restate
11 that I would see no reason why they wouldn't
12 retain them indefinitely.

13 Q. Okay. I just want to go back
14 for one second to when you said several times
15 that -- you talked about your understanding
16 about how the DEA -- or your belief that the
17 DEA does not -- has never given approvals of
18 suspicious order monitoring systems, and you
19 said that the manual said you're not supposed
20 to and all that.

21 When did you start at the DEA?

22 A. 2004.

23 Q. Okay. When you refer to the
24 manuals, to the Diversion Control Manual, you
25 were referring to a manual that you read in

1 communication on page 32 of my report.

2 BY MR. NICHOLAS:

3 Q. Okay. Hold up. Yeah.

4 I just want to know -- I mean,
5 all I really wanted to know is did you put in
6 your report that Mr. Gitchel said in 1984
7 that the DEA doesn't approve --

8 A. No, I think I may have
9 misspoke. I think it was in regards to
10 stopping shipments of --

11 Q. Okay.

12 A. -- orders.

13 Q. Okay. All right. That's fine.

14 A. That's why I wanted to review
15 my report, to make sure.

16 Q. This was an instance where you
17 reviewed your report and found something --
18 and found something that I agree -- supported
19 my point, so that's good. I should let you
20 review your report more often.

21 A. Yeah, you tried to stop me.
22 But I just want to be factually correct.
23 It's an important subject.

24 Q. I appreciate it.

25 A. And I had a recollection that

1 that was discussed, but it was about stopping
2 an order, so...

3 Q. All right. So since we are
4 talking about sort of what -- since you just
5 sort of brought up the shipping requirement.

6 A. Yes, sir.

7 Q. First of all, just so the -- so
8 we've got it on the record, what do you
9 understand -- it's a weird word, because it's
10 a shipping requirement, but it really -- it's
11 a reference to not shipping.

12 So can you just explain what
13 the shipping requirement is to your
14 understanding?

15 A. Well, first, I've never --
16 there's never really been a formal term. A
17 shipping requirement, I don't know if that's
18 an industry term or just somehow got created,
19 but it never was referred to as just a
20 shipping requirement.

21 I mean, it's -- it's the mere
22 fact that when a company uses a suspicious
23 order system and identifies a suspicious
24 order, they don't ship that order until they
25 dispel the suspicion about it and whether or

1 not it's going to be diverted to ensure that
2 gets properly distributed.

3 Q. Okay. So let me ask a couple
4 of basic questions here.

5 Does the CFR or the regulations
6 related to the CFR on this subject say
7 anywhere that there is a requirement that
8 distributors not ship suspicious orders?

9 A. I think they give guidance to
10 distributors under the maintenance of
11 effective controls. Only saying that because
12 if a distributor discovers a suspicious
13 order, to ship it without dispelling the
14 suspicion, that kind of violates the
15 maintenance of effective controls.

16 So I don't want to say it's
17 just a commonsense interpretation, but to
18 identify something suspicious that is
19 suspicious of diversion and then just
20 shipping it without stopping it and
21 dispelling it, that's at the core of that
22 regulation.

23 Q. Does the --

24 A. And the law.

25 Q. Does the regulation say

1 anything about ship -- does the regulation in
2 words, words, say anything about shipping?

3 A. No, in words, the regulation
4 does -- and just the --

5 Q. It does or does not?

6 A. It does not say the word
7 "shipping."

8 Q. Okay.

9 A. But again, I go back to the
10 maintenance of effective controls, and
11 secondly, it's been since the day I started
12 at DEA, that's been the interpretation of the
13 DEA, and I think there's been several
14 communications, Mr. Rannazzisi's letters.

15 Q. Okay.

16 A. All the way back -- now I can
17 go back to Mr. Gitchel's letter in 1984,
18 about stopping an order because that was the
19 topic that I discussed -- that I confused on
20 your earlier question.

21 Q. Do you -- is it your testimony
22 that the decision as to whether to ship or
23 not to ship an order that's been reported to
24 the DEA is left to the discretion of the
25 distributor?

1 A. So I think the discretion on
2 whether to ship or not ship is solely the
3 decision of the distributor. The DEA doesn't
4 inform a distributor if or when to ship an
5 order or not to ship an order. So the answer
6 to that would be yes.

7 Q. And if a distributor asks the
8 DEA -- if the distributor came to the DEA and
9 said, we've got this order, we have questions
10 about it, should we ship it or not ship it,
11 the DEA won't answer that question?

12 A. So I'm not sure that I'm
13 comfortable speaking for the entire DEA, but
14 how I'd like respond to that is through my
15 experience and what has occurred in the past.

16 So there may be a time when you
17 receive a call from a registrant that may ask
18 a question like that or a similar question,
19 so generally, you can -- first, I would
20 always state there's two -- two situations,
21 and we're just going to talk about suspicious
22 orders -- or, I mean, about distributions.

23 And first, I'll always state
24 that I can't tell a distributor when to ship
25 or not to ship, but I may ask a lot of

1 Q. Okay. And so when you refer to
2 flagged orders, you've got -- you know, your
3 top column, it's a grid.

4 A. Yep.

5 Q. And from left to right, across
6 the top, first it's the name of the
7 distributor. Then it says: Flagged orders
8 of oxycodone (dosage units). Then it says:
9 Flagged orders of hydrocodone (dosage units).

REDACTED



REDACTED

7 Q. So are you saying -- well, what
8 are you saying when you express this? I
9 shouldn't say.

10 I mean, you're showing it.
11 What does it mean?

12 A. So the methodologies applied to
13 the distribution, once the suspicious order
14 is identified, the criteria I used is if
15 there was no due diligence to dispel the
16 suspicious order or it wasn't reported, then
17 every subsequent distribution would be a
18 suspicious order.

19 Q. Let me -- I hate this
20 expression, but I'm going to have to unpack
21 that.

22 So the criteria you used -- you
23 say once the suspicious order is identified?

24 A. By the company -- or by the
25 methodology, I'm sorry.

1 Q. I mean, that's my first source
2 of confusion is, are these suspicious orders
3 or are these what you are suggesting should
4 have been suspicious orders, that you're
5 basing this on?

6 A. Well, it's not suspicious --
7 MR. FULLER: Objection to form.

8 A. It's not suspicious orders.
9 It's dosage amounts that resulted from
10 suspicious orders. So the methodology -- my
11 understanding of what Mr. McCann did -- and I
12 don't want to speak for him.

13 BY MR. NICHOLAS:

14 Q. Okay.

15 A. -- is he looks at the
16 distribution, the ARCOS data for the
17 distribution for AmerisourceBergen drug
18 company, he applies the methodology, and if
19 there are no suspicious orders, it just runs
20 along the distribution.

21 At some point, if there's a
22 month that exceeds the greatest month in the
23 previous six-month, that stops and it's a
24 suspicious order. So at that point, if there
25 was a due diligence to dispel that suspicious

1 order, if I could find that in my
2 investigation, then it would continue on.

3 If there was no due diligence
4 and, as my report details, there wasn't
5 during the early time periods -- during most
6 of the time period there was no due diligence
7 to dispel suspicious orders, so every
8 subsequent order would become a suspicious
9 order.

10 Q. On what basis are you saying
11 that there was no due diligence done to --
12 with regard to flagged orders? What is your
13 basis for saying that?

14 A. There were review of records
15 submitted on discovery.

16 Q. Records for --

17 A. Now, let me -- can I correct
18 this?

19 Q. Yeah.

20 A. I don't want to say none
21 whatsoever. I believe that probably there
22 may have been some individual instances of
23 due diligence, but in a general statement, at
24 a systematic level, there was insufficient
25 due diligence. Or none.

1 Q. And what is your basis for that
2 statement?

3 A. Reviewing records.

4 Q. Reviewing records provided to
5 you by the plaintiffs?

6 A. By the drug companies under
7 discovery.

8 Q. You only had access to the
9 records that the drug companies supplied in
10 discovery to the extent they were sent to you
11 by the plaintiffs' lawyers that were
12 retaining you, correct?

13 MR. FULLER: Object to form.

14 A. I'm not sure how to answer that
15 because I guess I hope I got all the records.

16 Now, I'm not indicating that I
17 looked at every one, but I looked at enough
18 to draw a conclusion or an opinion that there
19 was insufficient due diligence.

20 BY MR. NICHOLAS:

21 Q. Well, if you weren't sent
22 records that are -- that exist, how do you
23 know how many of the -- how many -- how do
24 you know whether you looked at a few, some,
25 most or all of the records? How do you know?

1 A. I think that's kind of a
2 hypothetical question.

3 Q. No, it's not hypothetical. You
4 told me that -- you told me that you obtained
5 records from plaintiffs' counsel, correct?

6 A. And it's my belief that I had
7 access to all the records. Now, there's no
8 way that I would know if that occurred or
9 not. That's -- I'm hopeful, as their expert
10 opinion, that I had access to all of the
11 records.

12 I can't affirmatively say that
13 they gave me every record. I -- that's why
14 it's kind of a hypothetical.

15 Q. Well, right now it is a
16 hypothetical because we really have no idea
17 what records you were provided, what records
18 you were provided and what you weren't
19 because I think you told us that you didn't
20 write down all the records that were provided
21 to you.

22 A. Well, I would say that in
23 regards to this matter, I reviewed sufficient
24 due diligence records to draw -- to make my
25 opinion.

1 Q. Now, sticking with that for a
2 minute, just because you did not review due
3 diligence records from 2010, 2011, 2012 --
4 let's assume you didn't see due diligence
5 records or as many as you would have liked.
6 That doesn't mean that the due diligence
7 wasn't done, does it?

8 A. Well, as far as the DEA is
9 concerned, if there's no documentation or
10 record of it, a due diligence file, my
11 opinion would be based on that that doesn't
12 exist.

13 Q. Well, we've already discussed
14 the fact that there was no requirement in the
15 regulations as to the retention of due
16 diligence records --

17 MR. FULLER: Object to form.

18 BY MR. NICHOLAS:

19 Q. -- for any period of time,
20 right?

21 MR. FULLER: Object to form.

22 That's not the witness's testimony.

23 A. So I don't think that's exactly
24 what my statement was. I think my statement
25 was is that it wasn't contained as a required

1 record in the recordkeeping section of the
2 CFR.

3 BY MR. NICHOLAS:

4 Q. Yeah.

5 A. But it was of my opinion that
6 it's covered under the maintenance of
7 effective controls, and it would be my
8 opinion as -- with my experience and my
9 training and my knowledge, is that it should
10 be kept forever. It's a historical record,
11 and it should be kept by the registrant much
12 greater than two years.

13 Q. Now, you keep saying that the
14 requirement to maintain records is contained
15 in the section pertaining to maintenance of
16 effective controls, but just so the record is
17 clear, there's nothing in the section on the
18 maintenance of effective controls that makes
19 any reference to records, correct?

20 A. Well, I --

21 MR. FULLER: Form.

22 A. I think within the statements,
23 that's what that statement means.

24 BY MR. NICHOLAS:

25 Q. Means. But I'm asking whether

1 you go right down each company, all right.
2 You've got one, two, three, four, five
3 companies, and in the case of each one,
4 you've got a parenthetical that says that
5 somewhere between -- that identifies
6 somewhere between 86.5% and 95.3% of total
7 dosage units, okay?

8 A. Yes, sir.

9 Q. All right. And that means
10 what? Is that the number of dosage units
11 that in your opinion should not have been
12 shipped?

13 A. Well, in my report, if we -- I
14 actually make a statement in regards to that
15 on page 46.

16 Q. Okay.

17 A. So it starts after the
18 footnote 151: However, it is my opinion to a
19 reasonable degree of professional certainty
20 that applying the tests set forth in the
21 Masters Inc. and Drug Enforcement
22 Administration provides a reasonable estimate
23 and initial trigger on a first step to
24 identifying orders of unusual size.

25 Q. So are you saying that --

1 A. Well --

2 Q. -- this is the number of --

3 MR. FULLER: Well, go ahead and
4 finish your answer.

5 MR. NICHOLAS: Okay. I thought
6 you were done. Sorry.

7 A. So -- and I can read the rest
8 of the paragraph.

9 BY MR. NICHOLAS:

10 Q. Don't read. I'd rather you
11 just tell me just in words, in your words,
12 what -- you know, what is it you're trying to
13 convey here?

REDACTED

REDACTED

5 Now, that --

6 Q. Okay. All right. So my
7 question is -- all right. So let me try
8 this.

9 Are you suggesting in your
10 report that more orders should have been
11 reported as suspicious?

12 A. Well, I don't think it suggests
13 that. I'll restate it again.

14 So when the system triggers a
15 suspicious order, it doesn't reset to the
16 next order to be a suspicious order. So how
17 I interpret the regulations and how my
18 training is and how the Masters ruling and
19 some of the documents I've read in regards
20 from McKesson and Cardinal and Prevoznik's
21 deposition testimony, is that once a
22 suspicious order is identified by registrant,
23 it should be stopped and there should be a
24 due diligence to dispel whether or not that
25 suspicious order is in fact suspicious.

1 If the registrant takes no
2 action and just continues to ship subsequent
3 orders in that order, then they're all
4 suspicious orders.

5 Now, my last paragraph kind of
6 sums up that this is how I applied this, and,
7 you know, it's in regards to how the court
8 would or would not accept it and there would
9 be other methodologies. So that's how I
10 interpret it.

11 Q. You know, on this subject I
12 think -- well, are you able to tell us -- are
13 you able to -- well, let's see.

14 Let's say an order is
15 identified by a distributor as suspicious,
16 okay?

17 A. Yes, sir.

18 Q. And it's reported to the DEA as
19 suspicious.

20 A. Yes, sir.

21 Q. Okay. You agree that that
22 doesn't necessarily mean that that order --
23 that the pills associated with that order are
24 going to be diverted, right?

25 A. No, I think that's exactly what

1 it means.

2 Q. You think every time that an
3 order is reported as suspicious that those
4 pills turn out to be diverted?

5 A. I don't know that I could draw
6 that conclusion, but I --

7 Q. That's the conclusion I'm
8 asking you about.

9 A. Well, I wouldn't draw that
10 conclusion. The only conclusion I would draw
11 is that if a registrant is adhering to the
12 law and the regulations and has a suspicious
13 order system in place and their system
14 identifies that, I would hope that they
15 believe that they're reporting to the DEA
16 what they believe to be a suspicious order.

17 Q. I'm asking you a completely
18 different question, okay?

19 My question to you is: When an
20 order was reported as suspicious -- strike
21 that. Strike that, because I -- I asked a
22 confusing question.

23 I think what you're saying is
24 that there are -- but tell me if I'm wrong --
25 is that more orders should have been reported

1 as suspicious than were reported; is that
2 right?

3 A. No.

4 Q. Okay. So you think that the
5 appropriate number of orders --

6 A. I --

7 Q. -- into Track 1 and Track 2
8 jurisdictions that were reported as
9 suspicious was indeed appropriate, that the
10 right number was reported?

11 A. This methodology doesn't look
12 at it that way because there was no due
13 diligence so --

14 Q. Hold on. Let me stop you
15 there.

16 MR. FULLER: Well, object --

17 MR. NICHOLAS: Go ahead. No,
18 I'm sorry. You're right. You're
19 right. Go ahead.

20 A. Because there was no due
21 diligence. So the methodology is not applied
22 to identify future orders that are
23 suspicious, because when you don't dispel the
24 suspicion or the potential that it's going to
25 be diverted and you can clear it to say that

1 it's not going to be diverted, then every
2 subsequent order, in my -- in the way I've
3 applied this, would be a suspicious order
4 based on the policies and the guidance and my
5 experience with the DEA.

6 BY MR. NICHOLAS:

7 Q. So your entire analysis here
8 rests on the premise that no due diligence
9 was done on the orders that you're reporting
10 on here; is that right?

11 MR. FULLER: Object to form,
12 misstates his prior testimony.

13 A. No -- either no or insufficient
14 due diligence.

15 BY MR. NICHOLAS:

REDACTED

REDACTED

5 So it's -- you know, the
6 critical thing I think that we -- that, you
7 know, that we are having trouble
8 communicating --

9 Q. We're definitely not
10 communicating right now and I'm sure I'm
11 not understanding this.

12 A. -- back and forth is the
13 concept that when you don't do due diligence,
14 that that makes every subsequent order a
15 suspicious order.

16 Now --

17 Q. That's what you're saying?

18 A. Yes, if there is insufficient
19 or there's incomplete or there's no due
20 diligence.

21 Now, that's a methodology
22 that's, I think, up to the court whether or
23 not to accept, but that's -- so it's just as
24 long as you understand clearly on how I had
25 this methodology applied.

1 Q. So again, your methodology
2 rests on your --

3 A. Opinion.

4 Q. -- conclusion or opinion that
5 either no due diligence was applied or
6 insufficient due diligence was applied -- you
7 know, was utilized by any of these companies,
8 and that results in these large numbers of
9 dosage units and these percentages; is that
10 right?

11 A. Yes, sir. My -- I'd like to
12 add to that as my final -- the final in
13 the -- on again, on 46, and this will maybe
14 be a clarification of what I said earlier,
15 the last sentence of the first paragraph: I
16 say this understanding that the litigation
17 will be advanced by selecting a methodology
18 qualifying a volume of pills that entered the
19 CT1 jurisdictions unlawfully and providing
20 this data to an economist to measure harm
21 caused by this volume.

22 Q. Yeah. You say in the -- the
23 first sentence of that paragraph says: I've
24 been asked to identify the number of opioid
25 pills that entered Cuyahoga and Summit

1 A. That's not what I respond --
2 how I answered the question just a couple of
3 questions ago.

4 So there could have been at
5 some point for each of these companies where
6 they designed or developed a system where
7 they met the regulatory and the legal
8 requirements. They had due diligence. They
9 had an effective system, and they began to
10 identify suspicious orders, and they -- they
11 did a -- more than a cursory approval and
12 they did due diligence. So that would stop
13 the count.

14 And then the methodology would
15 be applied again, and every one that was
16 identified, if there was effective due
17 diligence, it wouldn't be counted as a
18 distribution to the CT1.

19 Q. Did you stop the count at any
20 point in this analysis?

21 A. No, sir.

22 Q. And that's because you assumed
23 that there was no due diligence done at any
24 point from 1996 to your end date here --

25 MR. FULLER: Object --

1 BY MR. NICHOLAS:

2 Q. -- at least for the purposes of
3 your numbers?

4 MR. FULLER: Object to form.

5 A. It's not an assumption. It's
6 based on my review of records and depositions
7 and documents that I couldn't find a time
8 period where I believed there was sufficient
9 due diligence -- well, there was actually a
10 complete failure.

11 There was the failure to stop
12 suspicious orders, there was ineffective
13 suspicious order systems, but in regards to
14 what caused these large numbers, it was the
15 failure to have the maintenance of effective
16 controls to prevent diversion, which is the
17 act of the due diligence, the reviewing those
18 orders to approve them as was detailed in the
19 Masters opinion.

20 BY MR. NICHOLAS:

21 Q. Okay. Now, see if we can agree
22 on one thing here, which is this: There
23 could be an order of unusual size or
24 frequency or pattern that is shipped.
25 Whether it should have been or shouldn't have

1 been, we can put aside for another day.

2 Okay? Let's just say that there's an order
3 of unusual size, frequency, pattern, that, in
4 fact, was shipped and it -- you can even
5 say -- and let's say it should have been
6 reported as a suspicious order, but it
7 shipped. All right?

8 Do you agree that even though
9 that order was shipped and even though you
10 say it shouldn't have been shipped, it
11 doesn't necessarily mean that the pills that
12 underlie that order are going to be diverted.
13 You don't know.

14 MR. FULLER: Object to form.

15 BY MR. NICHOLAS:

16 Q. Correct?

17 A. So I'll answer that question by
18 saying that if it's identified as suspicious
19 order by unusual size or unusual frequency or
20 deviating form -- you know, substantial
21 deviation from a pattern, so to me that puts
22 it as a probable, greater than 51% that it's
23 going to be diverted because it's been
24 identified.

25 So I can't draw the conclusion

1 that I don't know that it's going to be
2 diverted. I probably can't draw a definitive
3 statement that it is, but I'm going to say
4 that it's more probable because the system
5 identified it.

6 Q. So you got it at 51% above,
7 it's going to be diverted; is that what
8 you're telling me?

9 A. Well, that's the definition of
10 probable. If it's an effective suspicious
11 order system, I believe the percents would
12 rise much higher than that, but I guess that
13 depends on the effectiveness of the
14 suspicious order system.

15 Q. Where are you getting that
16 percent from? Where are you getting that
17 from, just your own --

18 A. What?

19 Q. The 51, the probable, where are
20 you getting that it's probable?

21 A. That's my belief of what
22 probable means.

23 Q. Okay. Other than your belief,
24 is it written down anywhere? Is there any
25 research on that? Is there any data on that?

1 Is this just -- just your belief?

2 A. Not that I can cite.

3 Q. Okay.

4 MR. FULLER: Vegas odds.

5 MR. NICHOLAS: Okay.

6 BY MR. NICHOLAS:

7 Q. Did you look at any individual
8 orders from any pharmacies in the Cuyahoga or
9 Summit Counties?

10 A. I looked at some DEA 222 forms,
11 but I believe my recollection, it was out of
12 maybe the Boston area, so I would say no.

13 Q. Okay.

14 A. No original records. I
15 reviewed no original records.

16 Q. You reviewed data that was in
17 the aggregate, right, totals? Correct?

18 A. No. I reviewed -- so just so
19 we're clear on, you know, what we're talking
20 about, so there's no confusion.

21 Q. Uh-huh.

22 A. So to me, in the DEA world, an
23 original record is the actual DEA order form,
24 the invoice or a CSOS electronic order form.
25 So that's what I would consider an original

1 record. Also provided to me, there's the
2 ARCOS data, which is not an original record,
3 and there were some electronic databases that
4 appeared to me to be an electronic
5 spreadsheet or an electronic format of orders
6 that distributors or registrants had
7 submitted as part of the discovery. But none
8 of those would be what I would consider an
9 original record.

10 Q. Can you identify a particular
11 order from a particular pharmacy that you
12 believe should have been reported as
13 suspicious?

14 A. Well, in my assignment to
15 create this and do the investigation to come
16 to this opinion, there wasn't a requirement
17 for me to actually find specific orders that
18 were suspicious.

19 First of all, it would require
20 the use of the suspicious order system of the
21 registrant, like what would be the criteria.
22 The -- and the thing I found in doing my
23 opinion is that probably the most critical
24 part of setting up a suspicious order system
25 is the due diligence or sometimes in the

1 industry they call it the onboarding, and
2 that's to establish what the criteria is. I
3 said earlier what the usual is.

4 And I found it difficult
5 because I didn't really find an adequate
6 effort to set up what actually would be a
7 usual or what would be an expected order. So
8 for me to go in and try to make that kind of
9 analysis wouldn't be possible.

10 Q. So sitting here today, you
11 can't identify a particular order from a
12 particular pharmacy that should have been
13 reported as suspicious that wasn't; is that
14 correct?

15 MR. FULLER: Form.

16 A. I don't know because I didn't
17 task myself to do that.

18 BY MR. NICHOLAS:

19 Q. Sitting here today, can you do
20 it? I know you didn't -- I know it wasn't
21 part of your job description here. That's
22 all I want to know is can you do it today?
23 Is it part of your report?

24 A. Well, actually, let me retract.
25 I think I did that and I think it's on

1 A. Well, I guess I'm going to not
2 answer, not based -- well, based on his
3 instruction, but it's because whether it's a
4 fact that's known by -- discoverable by just
5 the general public, and I -- I don't know, so
6 that kind of makes me not want to answer that
7 question because I don't know if a person
8 could just do some query from the general
9 public and obtain that answer.

10 Q. Well, I can tell you that this
11 deposition is designated as a confidential
12 process to which the public does not have
13 access and will not have access.

14 So with that assurance, can you
15 answer the question now as to whether -- the
16 simple question of whether the DEA keeps
17 suspicious order reports on a database?

18 MR. FULLER: No, Counsel, hold
19 on one second. The Touhy request has
20 no bearing on whether this is kept
21 confidential or not. Touhy
22 authorization says he can't testify to
23 anything that is not publicly known
24 and that he gained information during
25 his employment. Touhy authorization

1 allows him to testify based on the
2 facts reviewed and provided in this
3 case. So I'm still going to give him
4 the same instruction.

5 I'll be honest with you, I
6 don't know if it's public knowledge or
7 not, whether it's in a database or
8 not. It may be.

9 MR. NICHOLAS: Okay.

10 BY MR. NICHOLAS:

11 Q. Do you agree with the statement
12 made by Mr. Rannazzisi in his deposition that
13 99% of doctors prescribe opioids for
14 legitimate medical purposes?

15 A. I don't really have an opinion
16 or I really don't agree or disagree. I don't
17 have sufficient knowledge or experience or
18 reviewed any studies to be able to make a
19 comment on that.

20 Q. And do you agree with the
21 statement made by Mr. Patterson of the DEA,
22 formerly of the DEA, testifying in front of
23 Congress that 99.9% of doctors are trying to
24 do the right thing?

25 A. My answer --

1 MR. FULLER: Form.

2 Go ahead.

3 A. My answer would be the same.

4 I -- I don't know the pure math of that
5 question, but with over 1 million doctors,
6 99.9%, I'm not sure --

7 BY MR. NICHOLAS:

8 Q. Do you think the vast majority
9 of doctors are trying to do the right thing?

10 MR. FULLER: Form, scope.

11 MR. NICHOLAS: You can answer.

12 A. I would agree with that, that I
13 have no experience or knowledge that says,
14 you know, anything otherwise than the vast
15 majority. I guess we could maybe dispute
16 about what vast majority is, but...

17 BY MR. NICHOLAS:

18 Q. When do you believe the opioid
19 crisis began?

20 A. I would probably say the onset
21 would be the Internet pharmacy activity, the
22 illicit Internet pharmacy activity, I think
23 1999, around in that time period.

24 Q. Okay. When did you first
25 become aware that there was an opioid crisis?

1 Around that time?

2 A. No. Probably when I started my
3 employment with the DEA in the academy.

4 Q. 2004?

5 A. Yes, sir.

6 Q. Is there a point at which you
7 believe the opioid crisis became common
8 knowledge?

9 A. Yes.

10 Q. When is that?

11 A. Well, could I get a
12 clarification of what you believe is common
13 knowledge? Because what's common knowledge
14 to me is -- would you -- would your
15 definition of that be just if you were to
16 stop somebody and say what is an opioid?

17 Q. How about known to government
18 entities, cities, towns, counties, states.

19 MR. FULLER: Form.

20 A. Well, I think it's -- I think
21 it probably coincided with when the Internet
22 pharmacy illicit conduct got to --
23 identified. There was a study that was being
24 done and it was published and showed the
25 conduct of these Internet pharmacies and

1 would consider to be overprescribing?

2 Because there's a couple of different ways I
3 think I could interpret that.

4 Q. Did doctors prescribe too many
5 opioid -- well, strike that. I'll try it
6 again.

7 A. Let me --

8 Q. Was there a period of time
9 when -- or do you believe doctors prescribed
10 more opioid pills than were medically
11 necessary for their patients?

12 MR. FULLER: Object to form.

13 He's not a medical doctor.

14 A. Well, my investigation into
15 some of them that I detailed as at least
16 bulleted in my report, would say that I would
17 ask -- answer that affirmatively because I
18 have some experience with doctors who did
19 issue illicit or diverted prescriptions.

20 So, you know, just in a general
21 answer would be yes. Now, I'm not going to
22 qualify that with how many or what, but
23 that's one of the essences of how diversion
24 occurs.

25 ///

1 BY MR. NICHOLAS:

2 Q. Are you able to tell -- well,
3 you wrote on your report on page 46, and we
4 read this already, that you had been asked to
5 identify the number of opioid pills that
6 entered Cuyahoga and Summit Counties
7 unlawfully, and then you went on to say it's
8 an impossible task, right? Page 46, first
9 full paragraph.

10 A. Yes.

11 Q. Okay. Are you able to tell us
12 the correct number of pills that should have
13 been shipped into Cuyahoga and Summit
14 Counties lawfully?

15 A. No, sir, I cannot provide that
16 information -- or did I calculate that
17 information or --

18 Q. Do you have any sense of it at
19 all?

20 A. Well, I'm supportive of my
21 opinion, and that's the failures by the
22 registrants during the time period was a
23 significant contribution to diversion and the
24 amount of pills. But to put a calculated
25 number, I can't do that. My methodology has

1 come to some conclusions based on, you know,
2 the due diligence factors.

3 Q. And in some regards, you'd
4 almost have to be a doctor to know an answer
5 to a question like that, right?

6 MR. FULLER: Form.

7 A. Well, I think that would be one
8 aspect, to be a doctor. But then, you know,
9 there's a lot of other factors that also
10 would be taken into consideration.

11 BY MR. NICHOLAS:

12 Q. But, I mean, you don't feel
13 qualified to look at a prescription for a
14 patient and know whether that prescription is
15 appropriate or not, correct?

16 A. Well --

17 MR. FULLER: Same objection.

18 A. I don't want to be
19 argumentative, but in my experience of doing
20 some cases, there have been instances where I
21 could look at a prescription, knowing how it
22 was written or the procedure that it was
23 used, and I could say that that was not a
24 legitimate prescription.

25 One example would be in one of

1 the cases I worked, patients would meet
2 doctors -- not patients. People would meet a
3 doctor in a parking lot, pay a hundred
4 dollars and get a prescription. So I don't
5 know that I would have to be a doctor to be
6 able to say that wasn't a legitimate
7 prescription.

8 BY MR. NICHOLAS:

9 Q. Fair enough. Sounds like
10 you're a little bit of a doctor, a little bit
11 of a lawyer and a little bit of a witness.

12 A. I just think that that doesn't
13 take either -- any of those quantifications
14 to say that there's something wrong with that
15 prescription.

16 Q. Okay. Just a little more, and
17 then I'll be done.

18 Now, you attended DEA basic
19 diversion investigator school in 2004; is
20 that right?

21 A. Yes, sir.

22 Q. Was that training at Quantico?

23 A. Yes, sir, it was -- I don't
24 want to say custodial training. It was a --
25 you actually stayed at the facility, 12-week

1 Q. Now, there are some customers,
2 isn't it true, who are going to consistently
3 order over these limits because they're large
4 customers; isn't that right?

5 MR. FULLER: Object to form,
6 vague.

7 A. Well, I guess that is a
8 possibility. I didn't see anything that
9 would not require an employee of Cardinal to
10 follow this procedure that would exempt any
11 type of customers or have them fail to take
12 this appropriate -- or this -- not
13 appropriate -- take this action as required.

14 BY MR. PYSER:

15 Q. What the policy says is on a
16 daily basis, cage-involved personnel should
17 be policing and identifying individual orders
18 that appear excessive in relation to what
19 other customers are buying and/or the
20 customer's purchase history. In these
21 situations DEA should be notified if possible
22 before the order is shipped and a copy of all
23 such orders should be maintained in the
24 division's suspicious order file, along with
25 the regulatory agency contact form noting any

1 specific instructions from DEA.

2 Correct?

3 A. Yes, sir.

4 MR. FULLER: And I don't know
5 what he's reading from, but if you
6 want to pull the policy to make sure
7 he's reading it accurately, you're
8 welcome to do so. I don't know --

9 MR. PYSER: Counsel, we can
10 drop the speaking objection. He's
11 already answered.

12 MR. FULLER: No, I won't drop
13 the speaking objections.

14 BY MR. PYSER:

15 Q. So let's take an example, the
16 Cleveland Clinic. They're in Cleveland,
17 Ohio. It's a large medical facility.

18 Would you expect the
19 Cleveland Clinic to order, when they order
20 from Cardinal Health, more than 800 capsules
21 of hydrocodone at a time?

22 A. I don't really have an opinion
23 either way. It's a possible reasonable
24 assumption, but without seeing the
25 distribution datas or the purchasing

1 requests, I don't know.

2 Q. And you haven't looked at that
3 information. You haven't gotten to that
4 level of granularity in your work?

5 MR. FULLER: Form.

6 A. I didn't review the Cleveland
7 Clinic or the ingredient limit reports for
8 specifically looking for the Cleveland
9 Clinic. I focused on the retail or the
10 pharmacies.

11 BY MR. PYSER:

12 Q. Do you believe that Cardinal
13 Health should have stopped shipping
14 hydrocodone and other pain medicine to the
15 Cleveland Clinic based on the fact that there
16 were times when the Cleveland Clinic ordered
17 more than 800 tabs of hydrocodone at a time?

18 A. So how I'll answer that is that
19 this policy was set up by Cardinal and it's
20 in response to how Cardinal identified the
21 scope of the businesses they supply.

22 So my opinion is based on the
23 policy that Cardinal set up. I didn't set up
24 this policy for them; they did. So if their
25 policy requires them to take an act and

1 they've set the limit up at 800 tablets, then
2 unless they modify their policy or they have
3 some exception, I -- this is their policy,
4 and this is what they're requiring their
5 employees to do.

6 Q. Sir, do you think that it would
7 be appropriate to deny cancer patients at the
8 Cleveland Clinic medication based on this
9 absolute limit? Yes or no?

10 MR. FULLER: Object to form.

11 That wasn't the same question.

12 A. Well, I think to answer that
13 question, if that did occur because they had
14 a defective suspicious order system, they
15 should correct that so that doesn't occur.

16 But so -- I guess that's a
17 hypothetical that I don't really want to
18 comment on, but the main thing that I want to
19 make sure is that -- on my statement is that
20 this is Cardinal's policy, and this is what
21 they're requiring their employees to do.

22 BY MR. PYSER:

23 Q. Sir, where do you get the
24 opinion that there was no flexibility around
25 this policy and Cardinal Health had no choice

1 specifically say it's something they did or
2 didn't do. I would just give them in some
3 matters guidance. It would be a guidance
4 that -- because in most regulatory
5 investigations, I may ask to see some due
6 diligence on a specific customer, and
7 sometimes it would come up when I asked for
8 it that they -- the registrant would tell me
9 that it's not a required record.

10 So the option was this is -- as
11 part of a work plan or a regulatory
12 investigation, a registrant wouldn't have to
13 show me the due diligence. In that case, I'd
14 have to subpoena.

15 BY MR. PYSER:

16 Q. You're one diversion
17 investigator when you were working at DEA,
18 correct?

19 A. Yes.

20 Q. Do you know one way or the
21 other whether the diversion investigators who
22 visited Cardinal Health's facilities ever
23 told them about this indefinite record
24 retention policy that you're putting forward
25 in your expert report?

1 MR. FULLER: Objection. And
2 remind you of your Touhy obligation.
3 Anything that is internal policy at
4 DEA or communicated while you were on
5 the job is outside the scope of what
6 you're authorized to testify to.

7 A. I'm not aware.

8 BY MR. PYSER:

9 Q. So on page 50 of your report,
10 you have a chart that talks about suspicious
11 orders reported in the CT1 jurisdictions,
12 right?

13 A. Yes.

14 Q. Okay. And there's two columns,
15 pre-shipment reporting and then -- on the
16 left, and on the right, post-shipment
17 reporting, right?

18 A. Right. Yes, sir.

19 Q. Okay. On the right side, the
20 post-shipment reporting, it's blank until
21 2005, correct?

22 A. Yes, sir.

23 Q. And that's blank there because
24 you know from testimony that Cardinal Health
25 was submitting ingredient limit reports to

1 DEA, but we just no longer have those
2 records; is that right?

3 A. Sir, I believe my report says
4 that I could not find those -- I could not
5 find -- those weren't provided to me and I
6 did not find those reports.

7 Q. You also reviewed the testimony
8 of Steve Reardon we talked about earlier
9 today, and he said Cardinal Health was
10 sending ingredient limit reports to the DEA
11 beginning in the early '90s, correct?

12 A. I don't have a recollection of
13 that exact statement in his deposition.

14 Q. Did you have any reason to
15 believe Mr. Reardon wasn't telling the truth
16 if that is, in fact, what he said?

17 A. No, I don't have any
18 independent knowledge of not -- whether to
19 believe him or not to believe him.

20 Q. So on page 50 we have blanks
21 under post-shipment report, where it's
22 unknown, but you filled in zeros on the left
23 side for pre-shipment reports all the way
24 from 1996 to 2012, correct?

25 A. Yes.

1 Q. We talked earlier about these
2 agency contact forms for phone calls to DEA?

3 A. Yes, sir.

4 Q. Is it possible that at some
5 point from 1996 through 2012 employees from
6 Cardinal Health may have called DEA before
7 shipping an order that was destined for
8 Cuyahoga or Summit County?

9 A. If that occurred, I would have
10 an expectation to see one of the agency
11 contact forms.

12 Q. But knowing that we don't have
13 any agency contact forms from Wheeling, West
14 Virginia, is it possible that people spoke on
15 the phone, but today, from 1996, it's
16 23 years later, so 23 years later, is it
17 possible a phone call was made but we don't
18 have a record of it?

19 MR. FULLER: Objection,
20 misstates evidence.

21 A. So I can only comment on the
22 facts of which I know and what records exist.
23 I don't make comments on hypothetical
24 situations of whether it could have occurred
25 and there was no documentation or it's lost

1 diligence, but that wasn't the program, and
2 it was just one occurrence, then I don't
3 think it's really faulty.

4 I think it requires that the
5 company acted -- actually had to have some
6 procedure in place to actually do due
7 diligence investigations, not just one
8 instance.

9 Q. But in your report you assume
10 that there was no due diligence and that
11 Dr. McCann then relied on that assumption,
12 correct?

13 And so my question is very
14 specific: If McKesson conducted sufficient
15 due diligence on that first flagged order
16 under its LDMP program, its CSMP program, its
17 Section 55 program, you would agree sitting
18 here today that the results that we see from
19 Dr. McCann's analysis, they would be
20 different?

21 MR. FULLER: Object to form,
22 misstates the fact. The witness
23 didn't make the assumption there was
24 no due diligence. He's testified
25 based on his opinion there's not

1 adequate due diligence.

2 A. That's hypothetical. I
3 wouldn't say one -- one due diligence would
4 reset it if the company's conduct continued
5 along the same, the same level, so -- and
6 my -- and my requirement to Dr. McCann was
7 that during the entire time period, I did not
8 see a sufficient due diligence to satisfy the
9 regulatory requirements, so that's why it was
10 ran during the whole time frame.

11 BY MR. EPPICH:

12 Q. How many due diligence
13 investigations or analyses would be enough to
14 be sufficient due diligence?

15 A. Every one of the suspicious
16 orders.

17 Q. Did you review any of the
18 flagged orders from Dr. McCann's analysis of
19 McKesson?

20 A. No, sir.

21 Q. Do you intend to offer any
22 opinions on whether the orders flagged by
23 Dr. McCann are legitimate or suspicious?

24 A. If that requirement is required
25 of me by the attorneys in the case, I would

1 complete that analysis. I don't have any
2 independent intentions of doing that.

3 Q. Sitting here today, you have no
4 opinions about the legitimacy of the flagged
5 orders from Dr. McCann's analysis, correct?

6 MR. FULLER: That misstates his
7 report.

8 A. It's -- Dr. McCann's report
9 doesn't report orders, it just reports dosage
10 units. It doesn't say how many orders. It
11 doesn't say there was an analysis of each
12 individual order.

13 It looked at them whether or
14 not they violated the trigger that was
15 provided for each one of them, and if it --
16 and then it moved forward without the --
17 because already knowing that there was
18 insufficient due diligence.

19 BY MR. EPPICH:

20 Q. And you reviewed -- let me
21 strike that.

22 Let's turn to page 74 of your
23 report. On page 74, I'm looking at
24 Section 6, the second paragraph in
25 particular. The first sentence there says:

1 There is no more effective control to prevent
2 diversion than blocking a suspicious order
3 before it is shipped.

4 Did I read that correctly?

5 A. You did, sir.

6 Q. And that's because a blocked
7 order of opioids remains safely in the vault
8 of the distributor's warehouse, correct?

9 A. I guess you could make that
10 assumption. It doesn't leave the control of
11 the distributor and have the potential to be
12 diverted, so I think that's probably the same
13 statement, yes, sir.

14 Q. You'd agree that reporting the
15 blocked order to DEA in a suspicious order
16 report does not prevent the blocked order
17 from being diverted, correct?

18 A. Well, that hypothetical
19 wouldn't occur because if you block an order
20 and report it, that doesn't -- unless you're
21 saying that that causes a distribution, and
22 if that causes the distribution without the
23 effective due diligence, then no, that would
24 not be true.

25 I would say that it would

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
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Tuesday, May 14, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, VOLUME 2, held at Weitz &
Luxenburg PC, 3011 West Grand Avenue, Suite
2150, Detroit, Michigan, commencing at
8:25 a.m., on the above date, before
Michael E. Miller, Fellow of the Academy of
Professional Reporters, Registered Diplomate
Reporter, Certified Realtime Reporter and
Notary Public.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | fax 917.591.5672
deps@golkow.com

1 there were questions related to the summary
2 data, I think I could answer any questions
3 related to that data because it's obviously
4 posted on the DEA website.

5 Q. All right. I'd like you to
6 turn to page 37 of your report, which I
7 believe you have in front of you.

8 A. It is.

9 Q. And I understand it's
10 Exhibit 16.

11 A. It is.

12 Q. Pages 37 through 40 of your
13 report are within a section that starts on
14 page 36.

15 Do you see that?

16 A. Yes, ma'am, titled Maintenance
17 of Effective Controls Against Diversion of
18 Controlled Substances.

19 Q. Yeah. And at the top of
20 page 37, just before the bullet list starts,
21 you wrote: Included below are some key
22 components that one would expect to see an
23 operational system designed to maintain
24 effective controls against diversion.

25 Did I read that correctly?

1 A. You did, ma'am.

2 Q. Okay. Then following that
3 statement at the top of page 37 of your
4 report, you've included a list, a
5 bullet-pointed list, several levels of bullet
6 points, that carries all the way over to
7 page 40.

8 Would you agree with that?

9 A. Yes, ma'am.

10 Q. Is that list of bullet points
11 on pages 37 to 40, is it your opinion that
12 those are requirements to be included in a
13 distributor's suspicious order monitoring
14 system?

15 A. No, I wouldn't say they're
16 requirements. As the initial statement said,
17 they would -- I would expect to see those as
18 components of an operational system, but it's
19 not a -- not dictating or saying that they're
20 a requirement by the government.

21 Q. You're not saying that any of
22 those bullet points on pages 37 through 40
23 are requirements, not a single one of them?

24 A. Oh, to meet the maintenance of
25 effective controls, I think they're all

1 requirements, but I understood your question
2 to say is this something that would be a
3 regulatory requirement, that something would
4 be in a regulation, these specific things.

5 Q. Let me --

6 A. Based on my experience, these
7 are all the things that I believe should be
8 present in a functioning operational
9 suspicious order system.

10 Q. Let me see if I understand your
11 testimony.

12 You're saying that the list of
13 components on pages 37 to 40 are not
14 requirements under the DEA's suspicious order
15 monitoring regulation; is that correct?
16 That's part one.

17 A. Well, the word "requirement" is
18 kind of the word that I'm thinking about. So
19 if you're trying to say that it's a mandate,
20 I would say in order for me to say that it's
21 an operational system, then these things
22 would need to be present. If they weren't
23 present, it wouldn't be an operational
24 system.

25 So if you were to say that you

1 could take this and say the DEA said you must
2 have these things in your system, there's a
3 possibility that maybe one of them wouldn't
4 be there and it still could function.

5 So I wouldn't say -- I don't
6 want to say that this is dictating exactly
7 what has to be in a system, but in my
8 experience in reviewing a lot of systems,
9 these would be the key components I would
10 expect to see.

11 Q. All right. Now I'm more
12 confused than I was before.

13 A. Okay.

14 Q. If I understand what you're
15 saying, it seems like you're saying the
16 bullet list at pages 37 to 40 are not
17 required by the DEA's suspicious order
18 monitoring regulation, but they are required
19 by the maintenance of effective controls
20 against diversion?

21 A. Let me start over. So --

22 Q. Just -- can you just say yes or
23 no? I really want to just know if I'm
24 following you.

25 MR. FULLER: No, he can explain

1 clarify.

2 MS. SWIFT: All right. Let me
3 see if I can clean this up.

4 MR. FULLER: Sure.

5 BY MS. SWIFT:

6 Q. There was a pronoun in the
7 question that I thought Mike was correcting.

8 When you say -- let's see. The
9 maintenance of effective controls is in the
10 large regulation which is above, or the
11 hierarchy, did you mean 1301.74(a)?

12 A. Well, that is the regulation.
13 I'm also aware that the laws in 823, USC 823.

14 Q. As your counsel just reminded
15 you?

16 A. Well, I've always known that
17 whether counsel reminded me or not.

18 Q. Understood. Understood.

19 A. So that's the regulation, it's
20 both the law regulation and the law. Only --
21 1301.74(b) is only a regulation, which is
22 part of the security program, which is part
23 of maintenance of effective controls.

24 So it's kind of bulleted so
25 that the top regulation is maintenance of

1 effective controls. Falling under that is
2 suspicious order system.

3 Q. So the list on 37 to 40, these
4 are not requirements under 1301.74(b), the
5 suspicious order monitoring regulation,
6 correct?

7 A. So I'd like to answer that by
8 saying I believe these are all components,
9 which would be necessary to have an effective
10 suspicious monitoring -- a suspicious order
11 monitoring system.

12 Q. And with respect, sir, that's
13 not what I asked you.

14 Are the bullet list components
15 on pages 37 to 40 of your report required
16 under 1301.74(b), the suspicious order
17 monitoring --

18 A. Yes, they are.

19 Q. Okay. All of them?

20 A. Yes.

21 Q. Okay. Great. Thanks.

22 Is it possible to have a
23 compliant suspicious order monitoring system
24 without all of these components?

25 A. Yes, I think it would be

1 possible.

2 Q. But they are all requirements?

3 A. Based on -- depending on the
4 scope of the business that's the customer and
5 based on the scope of activity of the
6 distributor, I would say that some of
7 these -- there could be some of these that
8 would not be necessary. But I'd also say
9 that there may be some that aren't identified
10 on this list. And also, based on the fact
11 that the distribution activity is not static
12 and it changes.

13 Q. So if I'm following you, all of
14 the bullet-listed components on pages 37 to
15 40 are, in fact, required under 1301.74(b),
16 but you could have a compliant suspicious
17 order monitoring system without all of these
18 compliant -- components, and, in fact, there
19 may be other components that are required
20 under 1301.74(b) that are not included in
21 this list.

22 Do I have all that, correct,
23 sir?

24 A. I believe that's correct, yes.

25 Q. Okay.

1 A. I'm not saying this is an
2 exclusive list and there might not be other
3 things that I have not considered or might
4 come up based on the type of business
5 activities that are involved.

6 Q. On page 39, if you would take a
7 look, please. You say, the top bullet, that:
8 A robust and well-documented due diligence
9 program is key.

10 And then it goes on from there
11 and provides components that you say you
12 would like to see in a due diligence
13 compliance program for suspicious orders,
14 correct, sir?

15 A. Yes, ma'am.

16 Q. Is it your opinion that a
17 distributor has to do all of the diligence
18 steps listed here in order to comply with the
19 law?

20 A. Yes, ma'am.

21 Q. All right. I want you to hold
22 on to these pages of your report for a
23 minute, please. And I'm going to hand you a
24 document. This will be Exhibit 19.

25 (Whereupon, Deposition Exhibit

1 Rafalski-19, 5/17/06 Corso Letter,
2 WAGMDL00753477 - WAGMDL00753479, was
3 marked for identification.)

4 MR. FULLER: Are they all the
5 same?

6 MS. SWIFT: They're all the
7 same.

8 MR. FULLER: Okay.

9 BY MS. SWIFT:

10 Q. Okay. Exhibit 19 is a
11 May 17th, 2006 letter from the DEA to Todd
12 Polarolo at Walgreens in Perrysburg, Ohio,
13 correct, sir?

14 A. Yes.

15 Q. Do you recognize this as a
16 letter the DEA sent to Walgreens after an
17 audit of Walgreens' Perrysburg, Ohio
18 distribution center in 2006?

19 A. I recognize it only based on my
20 review of documents for preparation of this
21 is the first time I've seen this, from my
22 report.

23 Q. You're mentioned in the first
24 paragraph of the May 17th, 2006 letter,
25 correct, sir?

1 A. I was there, yes, ma'am.

2 Q. When you were at the Detroit
3 field office, you were involved in this audit
4 of Walgreens' Perrysburg, Ohio distribution
5 center, correct, sir?

6 A. Yes, ma'am.

7 Q. This was a routine audit before
8 Walgreens' Perrysburg distribution center
9 started distributing Schedule II controlled
10 substances in early 2007, correct, sir?

11 A. No, that's not correct.

12 Q. What is the basis of your
13 statement that that's not correct?

14 A. It's a regulatory audit, but it
15 was just scheduled as part of the work plan
16 program. It wasn't in response to the second
17 part of your question, Schedule II controlled
18 substance authorization.

19 Q. Are you offering that testimony
20 based on your personal involvement with an
21 investigation of Walgreens while you were at
22 the DEA?

23 MR. FULLER: Again, I remind
24 you, Mr. Rafalski, that your
25 authorization does not and

1 specifically addresses the fact that
2 Walgreens was an investigation that
3 you conducted that you're not
4 authorized to talk about it based on
5 your personal knowledge. Just from
6 what information you gained in this
7 litigation.

8 BY MS. SWIFT:

9 Q. Do you want to retract the
10 testimony that you gave a moment ago?

11 A. Yes, thank you.

12 Q. This 2006 letter that I marked
13 as Exhibit 19 that the DEA sent to Walgreens
14 does not include the three pages of guidance
15 on what Walgreens' suspicious order
16 monitoring system should look like that you
17 included in your report at pages 37 to 40,
18 does it, sir?

19 A. It does not.

20 Q. This 2006 letter the DEA sent
21 Walgreens, it says what DEA thought Walgreens
22 was doing wrong. It doesn't provide an
23 explanation of what we should do to do it
24 right, correct, sir?

25 A. That's an accurate description

1 of what the letter says, yes, ma'am.

2 Q. You did not provide to
3 Walgreens the three pages of requirements
4 that are included in your report. You didn't
5 give those to Walgreens in 2006, correct,
6 sir?

7 MR. FULLER: Object to form.

8 Don't answer that, that would be based
9 on your own investigation, not
10 knowledge of this case.

11 BY MS. SWIFT:

12 Q. You're not going to come to
13 trial and say you provided these three pages
14 of guidance to Walgreens in 2006, correct,
15 sir?

16 A. If the Touhy is still in place,
17 I would say that I would not be able to
18 testify to that.

19 Q. You worked with the folks at
20 Walgreens' Ohio distribution center for
21 several years, correct, sir?

22 A. I'll respond to that question
23 by saying as part of my assignments as a
24 diversion investigator, I went on-site to
25 that facility several times. I'm not sure I

1 would agree that I worked with them, but I
2 was present at the registered location.

3 Q. You worked with Steve Kneller a
4 fair amount? He works at the Perrysburg
5 distribution center.

6 A. I know the name Mr. Kneller. I
7 think it's K-N-E-L-L-E-R?

8 Q. Correct.

9 A. I recognize that he was the
10 person that if I was on-site, that he would
11 be the person that I would have contact with,
12 yes, ma'am.

13 Q. Did you know Justin Joseph as
14 well?

15 A. There was another -- there was
16 one other person with him, and I don't know
17 that that was Mr. Joseph. I do remember who
18 Mr. Polarolo was, but I'm not sure.

19 Q. You never told Steve or Justin
20 or Todd Polarolo or anybody else at the
21 Perrysburg distribution center, here's a list
22 of things your suspicious order monitoring
23 system is supposed to have, did you, sir?

24 MR. FULLER: Object to form.

25 I'd remind you of your Touhy

1 authorization.

2 THE WITNESS: Based on the

3 Touhy, I'm not going to answer.

4 BY MS. SWIFT:

5 Q. You don't say anything like

6 that -- strike that.

7 The DEA doesn't say anything
8 like that in this 2006 letter, correct, sir?

9 A. None of the things that are in
10 the pages we've discussed is present in this
11 letter.

12 Q. You also don't say in your
13 report that you told Walgreens at any point
14 in time, here's what your suspicious order
15 monitoring system is supposed to look like?

16 A. My report does not indicate
17 that I told them that, that's a correct
18 statement.

19 Q. Did anything prevent you from
20 providing these pages of guidance on
21 suspicious order monitoring to Walgreens in
22 2006 or at any other point in time?

23 MR. FULLER: Object to form.

24 If it would deal with internal DEA
25 policies and what agents were and were

1 not allowed to do, you're not
2 authorized to answer that.

3 THE WITNESS: I think based on
4 the Touhy, I'm not going to answer
5 that question.

6 BY MS. SWIFT:

7 Q. Your position today, 13 years
8 after this 2006 letter from the DEA to
9 Walgreens, your position today after you've
10 been hired by the plaintiffs' lawyers and
11 paid to offer opinions in this case is that
12 these pages of your report, these three pages
13 listing these requirements, are all obligated
14 by law; is that right, sir?

15 A. I think I've always believed
16 they were obligated by the law. I would
17 probably say in 2006, the environment in
18 regards to the opioid crisis and diversion,
19 probably the environments changed.

20 So I'm not sure that all of
21 these would have been something that I would
22 have used or been aware of at that time.

23 I think this is fluid and it's
24 changed over a period of years, but
25 generally, the answer to your question...

1 Q. My question is simply: Do you
2 agree with me that the formula in
3 Appendix E(3) that Walgreens used to report
4 suspicious orders from 2007 to 2012 is not
5 the same as the customer grouping formula
6 Walgreens was using in 2006?

7 A. Well, this statement just goes
8 to say that they used the same multiplier, so
9 the three multiplier is the same as the E(3)
10 as it is in the area referenced in the prior
11 time period.

12 Q. The two formulas are not the
13 same, correct, sir?

14 A. The formulas are not, but the
15 multiplier is.

16 Q. Okay. That's all I'm trying to
17 get an understanding from you is whether the
18 customer grouping formula that Walgreens was
19 using when it received the 2006 letter from
20 the DEA is the same or different from the
21 formula it changed to use afterwards?

22 A. There's no customer grouping in
23 the subsequent years --

24 Q. Thank you.

25 A. -- starting in 2007.

1 Q. You didn't do -- well, strike
2 that.

3 You don't say in your report
4 that you or anyone else at the DEA ever told
5 Walgreens not to use the formula found in
6 Appendix E(3) of the Chemical Handler's
7 Manual, correct, sir?

8 A. Appendix E(3) was never
9 discussed in my presence with Walgreens.

10 Q. The DEA's 2006 letter to
11 Walgreens doesn't say not to use the E(3)
12 formula, correct?

13 A. I still stand by my previous
14 statement. The E(3) appendix was never
15 discussed by me or anyone in my presence the
16 whole time I was at Walgreens.

17 Q. And it's not mentioned in this
18 letter either?

19 A. It is not mentioned in that
20 letter.

21 Q. All right. I'd like you to
22 turn to page 40 of your report, please. Is
23 that 40?

24 A. I'm sorry.

25 Q. I believe you testified

1 yesterday that you did not review any of the
2 flagged orders from Dr. McCann's analysis; is
3 that correct?

4 A. I think my testimony in that
5 area was any specific orders. That would be
6 correct of what my testimony was, yes.

7 Q. You did not do any analysis to
8 see whether any specific suspicious order
9 caused the diversion of any specific pills
10 for nonmedical use, correct?

11 A. In regards to Dr. McCann's --

12 Q. Correct.

13 A. That would be a correct
14 statement. I didn't do a specific order of a
15 specific drug, if I understand your question
16 properly.

17 Q. Well, you asked for a
18 clarification of whether I was speaking about
19 Dr. McCann's analysis.

20 You didn't do any analysis to
21 see whether any specific suspicious order
22 caused the diversion of any specific pills,
23 correct?

24 MR. FULLER: Object to form.

25 A. I think that's an accurate

1 statement.

2 BY MS. SWIFT:

3 Q. You testified yesterday that
4 you endorsed Flagging Method A, which you can
5 see at the top of page 41 of your report.
6 Because it -- is that correct?

7 A. I think that's an accurate
8 statement. It was -- I endorsed it because
9 it was utilized by the Masters
10 Pharmaceutical.

11 Q. Is that the only reason you
12 endorsed Flagging Method A?

13 A. No, that wouldn't be the only
14 reason, no, ma'am.

15 Q. Did any of the plaintiffs'
16 lawyers instruct or suggest to you that you
17 use Flagging Method A?

18 A. No.

19 Q. What other reasons did you
20 endorse Flagging Method A?

21 A. One, it was part of one of the
22 investigations I conducted, so I was familiar
23 with it. I believe it was discussed at an
24 administrative hearing with the DEA,
25 subsequently reviewed by the D.C. Court, and

1 there was a ruling on it from the D.C. Court
2 and also the one ruling that it was part of
3 this litigation, I think...

4 Q. Discovery Ruling 12?

5 A. Yes, Discovery Ruling 12. So I
6 think it's had some scrutiny. I think it
7 would be the proper one. And that's...

8 Q. What analysis, if any, did you
9 undertake to test each of the five flagging
10 methodologies and their ability to identify
11 suspicious orders?

12 A. Could you say that one more
13 time, please?

14 Q. Sure.

15 What analysis, if any, did you
16 do to test the five flagging methodologies in
17 your report and their ability to identify
18 suspicious orders?

19 A. I didn't personally do any
20 tests. I'm aware that they could have been
21 done by Dr. McCann, but I didn't personally
22 do them.

23 Q. Do you know whether Dr. McCann
24 conducted any analysis at all to test the
25 five flagging methodologies and their ability

1 to identify suspicious orders?

2 MR. FULLER: Object to form.

3 A. He had an extensive report.

4 I'm not sure on that. I believe he did, but

5 I'm not sure.

6 BY MS. SWIFT:

7 Q. Why do you believe Dr. McCann
8 did any analysis at all to test the five
9 flagging methodologies and their ability to
10 identify suspicious orders?

11 MR. FULLER: Object to form.

12 A. Well, I think that's what this
13 does.

14 BY MS. SWIFT:

15 Q. You think that's what what
16 does?

17 A. I think the methodology of A
18 identifies suspicious orders based on that
19 methodology, and then it provides them in
20 dosage units. So I think ultimately, for
21 these dosage units to appear on this page,
22 there had to be flagged suspicious orders.

23 Q. You're pointing to a page of
24 your report, not Dr. McCann's report,
25 correct, sir?

1 A. Right. But -- yes. But for me
2 to see this --

3 MR. FULLER: Form.

4 A. -- I would have to know that
5 this methodology had flagged suspicious
6 orders because that's the only way the dosage
7 units could appear on this chart.

8 BY MS. SWIFT:

9 Q. Did you read Dr. McCann's
10 report?

11 A. I did.

12 Q. When did you read Dr. McCann's
13 report?

14 A. Sometime after he had submitted
15 it and reviewed his charts resulting from his
16 analysis.

17 Q. Did you read Dr. McCann's
18 report before you put together this section
19 of your report that appears at page 41?

20 A. No.

21 Q. Flagging Methodology A -- I'm
22 still at page 41 of your report. I'm going
23 to focus on the rows of these tables that
24 we've got here that relate to my client,
25 which is Walgreens, okay?

1 A. Sure. Yes, ma'am.

2 Q. Flagging Methodology A flagged
3 [REDACTED] of all Walgreens orders by dosage unit of
4 oxycodone and hydrocodone, correct, sir?

5 A. Yes, ma'am.

6 Q. Is it your professional opinion
7 to a reasonable degree of certainty that [REDACTED]
8 of Walgreens orders should not have been
9 shipped?

10 A. Based on the conduct of
11 Walgreens and the failure to do due diligence
12 on suspicious orders, yes, ma'am.

13 Q. Is it your opinion to a
14 reasonable degree of certainty that only [REDACTED]
15 of orders from Walgreens stores should have
16 been shipped and available to fill
17 prescriptions for Walgreens patients?

18 A. Well, that would be the
19 converse of this statement, but based on
20 their conduct -- I'll go back again, based on
21 their conduct and their failure to do
22 diligence after identification of suspicious
23 orders, the only conclusion I can draw is
24 that subsequent to that act, all of the
25 controlled substances were diverted.

1 Q. So that's a yes, your opinion
2 is that only [REDACTED] of orders from Walgreens
3 stores should have been shipped and available
4 to fill prescriptions for Walgreens patients?

5 MR. FULLER: Object to form.

6 A. I really don't know because
7 Walgreens didn't conduct the proper due
8 diligence. But based on the methodology and
9 how I applied it, that's the results of the
10 methodology.

11 BY MS. SWIFT:

12 Q. You don't know whether it's
13 true that only [REDACTED] of orders from Walgreens
14 stores should have been shipped and available
15 for prescriptions to be filled for Walgreens
16 patients?

17 A. I guess you would draw that
18 conclusion based on [REDACTED] based on the
19 conduct of Walgreens, yes, ma'am.

20 Q. You would draw the
21 conclusion --

22 A. I would draw the conclusion
23 based on --

24 Q. Let me ask the question so the
25 record is clear.

1 You would draw the conclusion
2 that only █ of Walgreens orders should have
3 been shipped so that prescriptions could be
4 filled for Walgreens patients?

5 MR. FULLER: Object to form,
6 asked and answered. You've asked it
7 twice now or three times, probably.

8 A. Same as my previous statement.
9 Based on Walgreens' conduct in regards to
10 applying this methodology, that would be a
11 correct statement, yes, ma'am.

12 BY MS. SWIFT:

13 Q. You didn't do any analysis of
14 how many people would not have gotten their
15 medication if █ of Walgreens orders had not
16 shipped, correct, sir?

17 A. I did not.

18 Q. You didn't do any analysis of
19 how many legitimate prescriptions would have
20 gone unfilled if 95% of Walgreens orders had
21 not been shipped, correct, sir?

22 A. I did not do that analysis, no,
23 ma'am.

24 Q. In your report, you don't offer
25 an opinion on the legitimacy of any of the

1 other flagging methods you talk about,
2 correct?

3 A. That's correct.

4 Q. You didn't offer any criticisms
5 of any of the five flagging methods in your
6 report, correct, sir?

7 A. Oh, I think I did.

8 Q. Where did you offer criticisms
9 of any of the five flagging methods in your
10 report?

11 A. You're saying the
12 methodology --

13 Q. Correct.

14 A. -- for example, the three
15 times?

16 Q. There are five methodologies --

17 MR. FULLER: Go ahead and
18 finish your answer, Raf.

19 MS. SWIFT: Yes, I was
20 answering his question. There was no
21 pending question.

22 A. Yes. Throughout my report, I
23 think there's reviews of these methodologies,
24 and I think I'm critical of each of the
25 methodologies, with the exception of

1 data that it would have to indicate specific
2 orders which would identify those pharmacies.

3 Now, whether he looked at them
4 specifically to that pharmacy, but based on
5 your question, just the analysis of the ARCOS
6 data, that -- that actually would occur
7 because each order would be specific to a
8 pharmacy.

9 He didn't -- if I understand
10 your question, he didn't look at them in
11 terms of each specific pharmacy, but the
12 nature of the analysis, it is by the pharmacy
13 by the orders.

14 Q. You did not perform an analysis
15 to see whether Walgreens performed diligence
16 on any of the actual orders that flagged on
17 any of your five methodologies in
18 Mr. McCann's analysis, correct?

19 A. Well, my investigation and
20 opinion of Walgreens does state that in
21 regards to the due diligence topic.

22 Q. Listen to my question. That's
23 not what I'm asking about.

24 A. Okay.

25 Q. We'll get to the stuff you say

1 in your report about the due diligence that
2 Walgreens did.

3 You didn't perform an analysis
4 to see whether Walgreens performed diligence
5 on any of the specific orders that flagged on
6 any of these five methodologies, correct,
7 sir?

8 A. I'm not aware of any due
9 diligence for those orders, that's correct.

10 Q. That's not what I asked.

11 A. I didn't -- I didn't
12 specifically go to McCann's report and look
13 at each order of Dr. McCann's and try to find
14 due diligence. I just looked at the scope of
15 the due diligence by Walgreens.

16 Q. You didn't go to Dr. McCann's
17 report and look at any order of -- that
18 flagged on any of the analyses.

19 A. That's a correct statement.

20 Q. For any of the five flagging
21 methods that you talk about, did you consider
22 the impact of stocking a new store's shelves?

23 A. I did not take that specific
24 incident into consideration, but in my review
25 of due diligence records, I didn't find

1 anything that would indicate that that had
2 occurred.

3 Q. Did you consider whether any of
4 the five flagging methods that you talk about
5 could flag an order for a store before the
6 store even opened for business, just based on
7 the stocking of the store's shelves? Do you
8 know whether that happened?

9 A. I'm not aware that that had
10 happened.

11 Q. Did you read Dr. McCann's
12 testimony from this past Friday that using at
13 least some of these five flagging methods, an
14 order to stock a new store's shelves could be
15 flagged?

16 A. I don't recall reading that in
17 his testimony, no, ma'am.

18 Q. Did you read his testimony yet?
19 I know it was just the other day.

20 A. I've read so many. I don't
21 believe so.

22 Q. I will represent to you, and
23 you can check the transcript, that Dr. McCann
24 testified that for low-volume stores, the
25 store might never have another order as big

1 an economist or I've never talked to anyone
2 with the purpose of giving these things to an
3 economist. So I don't want to imply my
4 testimony is I've never talked to an
5 economist. I'm not aware of it, but I'm just
6 kind of protecting the fact that if I did, I
7 wasn't even aware of it.

8 Q. You never explained the data in
9 your report to anyone for the purpose of them
10 taking that data and using it to calculate
11 damages in this litigation?

12 A. I have never done that.

13 Q. You testified yesterday that
14 you provided the five flagging methods
15 discussed in your report -- you provided
16 those to plaintiffs' counsel by phone I
17 believe, you said to -- provided them to
18 Mr. Farrell.

19 Do you remember that testimony?

20 A. I think that question was the
21 first time that I talked to somebody about
22 it. So --

23 Q. I'm trying to get at how the --

24 MR. FULLER: Object to the form
25 of the last question. I'm sorry.

1 BY MS. SWIFT:

2 Q. I'm trying to get at how the
3 five flagging methods made their way from you
4 to Dr. McCann.

5 Do you have any idea how that
6 happened?

7 A. There was a couple of different
8 discussions with the plaintiff attorneys.
9 I'm not sure who relayed it to Dr. McCann. I
10 discussed it with Paul Farrell, Mr. Farrell a
11 couple of times; also with Mr. Fuller. I'm
12 not sure who relayed it to him, but I
13 discussed the methodologies and how I wanted
14 them applied.

15 Q. All of those conversations were
16 verbal, is that correct, not in writing?

17 A. There was nothing in writing,
18 and they were verbal, either in person or on
19 a telephone.

20 Q. I'm going to hand you what I'll
21 mark as Exhibit 20.

22 MS. SWIFT: And, Counsel, I
23 apologize, I only have one extra copy.
24 Blame the hotel. I'm not even going
25 to have a copy for myself.

1 (Whereupon, Deposition Exhibit
2 Rafalski-20, Plaintiffs' Responses to
3 the Amended and Clarified Discovery
4 Ruling 12 Supplemental Interrogatory
5 Issued to Plaintiffs, was marked for
6 identification.)

7 BY MS. SWIFT:

8 Q. Do you have that in front of
9 you, sir?

10 A. I do.

11 THE WITNESS: Trade you.

12 Sorry.

13 BY MS. SWIFT:

14 Q. Well, first of all, have you
15 ever seen the document that I've marked as
16 Exhibit 20?

17 A. I have, yes, ma'am.

18 Q. The document I marked as
19 Exhibit 20 is a set of interrogatory
20 responses served by the plaintiffs on
21 January 25th, 2019, and if you go to -- I
22 believe it's the sixth page -- there's a list
23 of flagging methodologies prepared at the
24 very end of the written interrogatory
25 response. Keep going.

1 MR. FULLER: It's not page
2 numbered.

3 MS. SWIFT: I noticed that,
4 Mike.

5 MR. FULLER: We'll blame
6 Mr. Moody or Mr. Farrell.

7 BY MS. SWIFT:

8 Q. Do you have a list in front of
9 you, Mr. Rafalski, that lists five flagging
10 methodologies in the plaintiffs'
11 interrogatory response from January 25th?

12 A. I do.

13 Q. Are these your five flagging
14 methodologies?

15 A. Yes, ma'am.

16 Q. Which one is based on the
17 Masters case?

18 A. 4.

19 Q. Am I correct based on your
20 testimony today and yesterday that you're not
21 planning to come to trial and offer testimony
22 about any of the flagging methods except the
23 Masters method?

24 A. No, I don't think that's my
25 testimony.

1 Q. Okay. All right. Turning back
2 to your report -- you can set that aside,
3 we're done with it -- page 42, I'd like to
4 take a look at, please.

5 MR. FULLER: I'm sorry,
6 Counsel, what page?

7 MS. SWIFT: 42.

8 BY MS. SWIFT:

9 Q. If you had picked Flagging
10 Method B that's identified at the top of
11 page 42, instead of Method A, the Masters
12 method, what data would you have presented
13 for Walgreens?

14 MR. FULLER: Object to form.

15 A. I don't understand that
16 question.

17 BY MS. SWIFT:

18 Q. Fair enough.

19 A. I think I did pick
20 Methodology B, but so I don't understand.

21 Q. Well, you said you endorsed
22 Method A and that's the only method you
23 endorsed, correct, because of the Masters
24 case and some other reasons?

25 A. Well, I think I make that

1 Q. You didn't --

2 A. -- trigger.

3 Q. You can't vouch for the
4 accuracy of any of the numbers that appear in
5 these tables at pages 41 to 45 of your
6 report, correct, sir?

7 A. Mr. McCann would have to
8 testify to the accuracy. He did the
9 analysis.

10 Q. You just relied on what
11 Mr. McCann provided, correct, sir?

12 A. Yes, I did.

13 Q. You were -- strike that.
14 You don't have an opinion about
15 whether any particular order that you
16 identified or that Dr. McCann identified as
17 suspicious was diverted to an illicit
18 channel, correct, sir?

19 A. Well, I think based on the
20 methodologies and the lack of due diligence,
21 I think my -- these say that those were
22 diverted.

23 Q. My question was a little bit
24 different.

25 A. Okay.

1 Q. You don't have an opinion about
2 whether any particular order -- you didn't
3 look at any particular order to see whether
4 it was diverted to an illicit channel?

5 A. I did not --

6 Q. Okay.

7 A. -- analyze all the orders and
8 try to find one or locate one that was
9 diverted.

10 Q. You didn't analyze any of the
11 orders, correct, sir?

12 A. That's correct.

13 Q. You have no opinion about
14 whether any particular order that was flagged
15 as suspicious led to someone's addiction,
16 overdose or death, correct, sir?

17 A. As of today, I have no opinion
18 on that matter.

19 Q. Do you plan on coming up with
20 that opinion at some point after today?

21 A. I can't rule that out if I'm
22 asked to look at that or I'm provided some
23 information I could review that would -- that
24 would indicate that. So I can't rule out
25 that that would occur.

1 Q. If a prescription was
2 legitimate, the pharmacist was obligated to
3 fill it, correct, sir?

4 MR. FULLER: Form.

5 A. I don't think the DEA speaks to
6 that, whether they're obligated to fill a
7 prescription.

8 BY MS. SWIFT:

9 Q. Do you know one way or the
10 other whether --

11 A. If the DEA speaks to that
12 topic?

13 Q. No, sorry.

14 Do you know whether pharmacists
15 are obligated by their professional
16 responsibilities to fill prescriptions that
17 they have determined are legitimate? Maybe
18 you don't know one way or the other.

19 A. Let me think. I don't know
20 that, the answer to that question.

21 Q. All right. Turn, if you would,
22 please, to page 114 of your report.

23 A. Can I qualify my last answer,
24 quickly?

25 Q. Sure.

1 Q. Is that the page 856 that you
2 cite in your report at page 114?

3 A. Yes, ma'am.

4 Q. Okay. This Appendix 10 from
5 McCann's report is what you relied on to
6 determine total volume of oxycodone and
7 hydrocodone that Walgreens shipped into
8 Cuyahoga and Summit Counties; is that right?

9 A. Yes, ma'am.

10 Q. You only talk about oxycodone
11 and hydrocodone in your report, correct?

12 A. Yes, ma'am.

13 Q. Am I right that you don't have
14 any opinions about any other opioid pain
15 medications besides oxy and hydro?

16 A. As of today I do not because I
17 was not requested to do any analysis on those
18 other drugs.

19 Q. After -- turn back to page 1 of
20 Exhibit 21. The page 1 of Exhibit 21 is a
21 table that shows overall numbers, Total
22 Shipments to Cuyahoga identified by
23 Methodology, Common Sense Method, Maximum
24 Monthly Trailing Six-Month Pharmacy Specific
25 Threshold, Walgreens to All Buyers, 1996 to

1 2018, correct?

2 A. Yes.

3 Q. And it's a table that shows
4 numbers broken out by drug and by
5 transaction, dosage units, MME, and base
6 weight, correct?

7 A. Yes.

8 Q. After the table on page 1 of
9 Appendix 10, there's a series of bar graphs
10 showing, in the aggregate, Walgreens
11 shipments of oxy and hydro to its pharmacies
12 in the aggregate, correct?

13 A. Yes, ma'am.

14 Q. None of these charts shows any
15 data for any individual Walgreens pharmacy,
16 correct?

17 MR. FULLER: Object to form.

18 A. That's an accurate statement,
19 but they're all built upon individual orders.

20 BY MS. SWIFT:

21 Q. I understand.

22 A. Okay.

23 Q. I'm just saying, when you're
24 flipping through Dr. McCann's charts that
25 display the results of his flagging

1 methodologies, you can't tell anything about
2 any individual pharmacy, correct?

3 A. I cannot by looking at these
4 charts.

5 Q. Do you know how many Walgreens
6 stores there are in Cuyahoga County?

7 A. I do not.

8 Q. How about Summit County?

9 A. I do not.

10 Q. Do you know anything about the
11 geographic locations of any of Walgreens'
12 pharmacies in Summit or Cuyahoga County,
13 other than the fact that they're in those
14 counties?

15 A. It doesn't appear in my
16 opinion, but during my review of data, I did
17 at one point take a look by just using the
18 Internet, Googling and looking at some of the
19 locations, but I didn't formulate a report on
20 that.

21 So I won't say that I never did
22 that, but I don't have any records or
23 documents that would record exactly the
24 distances and the locations.

25 Q. You also didn't include in your

1 report anything about the specific customer
2 base for any individual Walgreens pharmacy,
3 correct, sir?

4 A. I did not.

5 Q. Do you know how many of the
6 Walgreens pharmacies in Cuyahoga and Summit
7 County are on corner lots?

8 A. I do not.

9 Q. Do you know how many of the
10 Walgreens pharmacy in Summit and Cuyahoga
11 Counties are freestanding locations with
12 their own dedicated parking and a
13 drive-through window?

14 A. I do not.

15 Q. Do you know how much oxycodone
16 or hydrocodone Walgreens distribution centers
17 shipped to any one of those Walgreens
18 pharmacies?

19 A. I do not. I had not done that
20 analysis up to today.

21 Q. You can't tell any of that from
22 the charts that are in Appendix 10, correct,
23 sir?

24 A. That's correct.

25 Q. All right. You can set that

1 one aside.

2 Turn, if you would, please,
3 sir, to page 117 of your report. This is a
4 section within the Walgreens section about
5 the due diligence that you believe Walgreens
6 conducted, correct?

7 A. Yes, ma'am.

8 Q. Now, as I understand it, it's
9 your opinion that because you only saw a
10 limited number of e-mails about due diligence
11 that Walgreens performed 10, 12, 13 years
12 ago, that that means Walgreens performed no
13 other due diligence; is that correct?

14 A. Not that was brought to my
15 attention in trying to formulate my opinion.

16 Q. And in formulating your
17 opinion, you determined that Walgreens had
18 only conducted limited due diligence because
19 you only saw documentation of limited due
20 diligence, correct?

21 A. That's the only basis I could
22 use to form my opinion.

23 Q. You based your -- well, let me
24 ask you this.

25 Did you read any of the

1 this one?

2 MS. SWIFT: Yep.

3 (Comments off the stenographic
4 record.)

5 BY MS. SWIFT:

6 Q. I'm marking as Exhibit 25 an
7 excerpt of McCann's Appendix 11, and like
8 with the others today, what we've done is
9 pulled out the pages that relate to
10 Walgreens, okay?

11 A. Okay.

12 Q. Have you ever seen the charts
13 that appear in Exhibit 25?

14 A. I believe I looked at these
15 because they were part of the methodology
16 analysis.

17 Q. Who shared them with you?

18 A. I believe Mr. Elkins would have
19 provided them to me.

20 Q. The plaintiffs' lawyer,
21 Mr. Elkins?

22 A. Yes.

23 Q. When did Mr. Elkins share the
24 charts in Exhibit 25 with you?

25 A. I don't recall.

1 Q. You didn't cite or attach any
2 of these charts to your report, correct, sir?

3 A. No, I don't believe I did.

4 Q. You've never talked to
5 Dr. McCann about any of the charts in his
6 report; am I right about that?

7 A. That's correct.

8 Q. Okay. All right. You can set
9 those aside. That's all I was going to do
10 with that one.

11 Turn, if you would, please, to
12 page 115 of your report. Page 115 is within
13 the Walgreens section and talks about an
14 investigation of the Jupiter distribution
15 center in Florida, correct, sir?

16 A. It does at the bottom of the
17 page.

18 Q. You didn't have any personal
19 involvement in the Jupiter, Florida
20 investigation of Walgreens, correct?

21 A. No, ma'am, I don't believe so.

22 Q. To the extent that you have
23 opinions about the Jupiter, Florida
24 investigation, you're relying entirely on the
25 Order to Show Cause and related documents

1 attached to Walgreens' 2013 settlement
2 agreement with the DEA -- is that right --
3 cited in note 493?

4 A. Yes, ma'am.

5 Q. Okay. Did you -- in preparing
6 for your -- to write your report, did you
7 review any of the documents showing
8 Walgreens' efforts to cooperate with Florida
9 DEA and local law enforcement in 2010 and
10 2011?

11 Do you remember anything like
12 that?

13 A. I don't remember reviewing any
14 records or communications in regards to that,
15 no, ma'am.

16 Q. In preparing your report, did
17 you review any of the documents produced by
18 the plaintiffs, Cuyahoga and Summit County,
19 showing Walgreens' pharmacists notifying
20 local law enforcement when they suspected
21 diversion?

22 A. No, ma'am.

23 Q. Turn, if you would, please, to
24 page 118. I'll direct your attention to the
25 last paragraph on the page that starts

1 A. Yes.

2 Q. But if you look at the CVS line
3 for Cuyahoga County on page 41, you've got
4 [REDACTED] of the total dosage units are flagged
5 using the trailing six-month threshold?

6 A. I do.

7 Q. And you have [REDACTED] of the total
8 dosage units in Summit County that are
9 flagging, right?

10 A. I do.

11 Q. And if you remove the
12 assumption that everything after one failed
13 due diligence effort flags, do you know what
14 those numbers go down to?

15 A. I do not.

16 Q. You have no clue?

17 A. I have no clue.

18 Q. If I told you that in Summit
19 County they go down to [REDACTED] rather than [REDACTED],
20 and they go down to [REDACTED] rather than [REDACTED] in
21 Cuyahoga, would that surprise you?

22 A. I wouldn't have a comment on
23 those figures.

24 Q. Now, you also have testified
25 already a little bit about whether or not you

1 reviewed any particular orders, and I think
2 your answer in substance is no, you didn't
3 review any particular orders that might or
4 might not have been suspicious.

5 Is that generally true?

6 A. That's generally true, that's
7 my recollection is I answered that way
8 previously, too, yes, sir.

9 Q. And with respect to any of the
10 orders that are flagged by these
11 methodologies under your and Mr. McCann's
12 analysis, you don't know what happened to any
13 of the drugs that were actually shipped and
14 delivered to CVS Pharmacies?

15 A. I don't have any direct
16 knowledge of what happened to any of the
17 drugs that were distributed to each of the
18 pharmacies. I didn't conduct any analysis as
19 of today that would give me that knowledge.

20 Q. And you don't know whether -- I
21 understand that your opinion is that the due
22 diligence was insufficient by CVS, and we'll
23 get to that in a minute.

24 But you don't know whether any
25 of these orders would have cleared a due

1 diligence investigation that does meet your
2 exacting standards, do you?

3 A. Could you say that one more
4 time, I'm sorry?

5 Q. I'm just saying you don't know
6 whether any of the orders that are flagged
7 using your and Mr. McCann's methodologies for
8 CVS would have been cleared using what you
9 would say is an adequate due diligence
10 process. You haven't done that analysis.

11 A. So I think what you're asking,
12 is it a hypothetical question?

13 Q. Yes.

14 A. Okay.

15 Q. Well, no, actually it's not.
16 You don't know. I'm asking you. You don't
17 know?

18 A. Well, I guess you're asking me
19 to assume that if CVS had an adequate due
20 diligence system in place and they conducted
21 it? Is that the question? Maybe I don't
22 understand the question.

23 Q. Let's -- if you took your
24 standards for a due diligence system --

25 A. Okay.

1 that. It's just that I wasn't tasked to
2 provide that methodology in regards to
3 manufacturers at this time.

4 Q. I understand. But your report
5 doesn't identify any suspicious orders that
6 were submitted by distributors to
7 manufacturers.

8 A. My report would only identify
9 those orders that the manufacturers have
10 identified. I don't make any independent
11 calculations or apply any algorithms to
12 identify it outside of what's in my report
13 stated as I've discovered as part of this
14 discovery.

15 Q. Okay. So other than the
16 reports that the manufacturers themselves
17 reported to DEA, you have not identified any
18 suspicious orders submitted by distributors
19 to manufacturers, correct?

20 A. Can I ask a clarification? Are
21 you talking about an individual order or are
22 you talking about conduct?

23 Q. I'm talking about individual
24 orders.

25 A. I have not done that as we sit

1 here today, no, sir.

2 Q. Okay. So your report does not
3 identify any shipments by manufacturers to
4 distributors that you claim should have been
5 reported as suspicious?

6 A. My opinion goes to whether or
7 not there were effective -- or suspicious
8 orders, effective suspicious order systems in
9 place and/or the maintenance of effective
10 controls, the due diligence. I do not do any
11 calculations that would identify any specific
12 orders.

13 Q. Okay. So just to be clear, in
14 response to my question, your report does not
15 identify any shipments by manufacturers to
16 distributors that you claim should have been
17 reported as suspicious, correct?

18 A. I think there's some instances
19 in my report, there was -- there may be a
20 description of a relationship or some
21 transactions between a -- let me think a
22 second.

23 Q. Uh-huh.

24 A. Because I have all of the
25 different companies.

1 (Document review.)

2 A. I don't believe so, no, sir.

3 BY MR. O'CONNOR:

4 Q. Okay. And at trial, do you
5 intend to offer any opinion regarding whether
6 any particular order submitted to a
7 manufacturer was suspicious?

8 A. If I'm requested to do that
9 analysis by counsel, I guess that would be a
10 possibility. I haven't done the analysis as
11 today, so I couldn't offer that opinion.

12 Q. So as you sit here today, you
13 do not have an opinion on whether any
14 particular order that was shipped by a
15 manufacturer was suspicious?

16 A. I think I have an opinion.

17 Q. But you haven't identified any
18 order, correct?

19 A. I have not identified a
20 specific order, but I have an opinion on the
21 conduct.

22 Q. And are you offering any
23 opinion in this litigation that any
24 particular order that was shipped into Summit
25 or Cuyahoga Counties was suspicious?

1 A. Yes.

2 Q. Okay. And are you offering any
3 opinion in this litigation that any
4 particular order shipped by a manufacturer
5 into Summit or Cuyahoga County was
6 suspicious?

7 A. I'm sorry, shipped by a
8 manufacturer --

9 Q. Correct.

10 A. -- to a distributor?

11 Q. That's right. To -- to someone
12 in Cuyahoga or Summit County.

13 A. No, sir.

14 Q. Okay. With respect to a
15 manufacturer, what is a suspicious order?

16 A. Well, if a manufacturer has
17 conducted a sufficient due diligence or
18 onboarding process and they've evaluated the
19 scope of their customers' business and the
20 needs, they would establish a pattern, and
21 that pattern would give them an idea of
22 initially the volume of drugs they need to
23 purchase.

24 Now, if it's brand-new
25 customer -- yours is kind of a hypothetical.

1 If it's a brand-new customer, there's not a
2 pattern or a frequency, but they would start
3 out with what they assess as a legitimate
4 volume, and they would monitor that volume,
5 and if a customer exceeded that, that should
6 trigger as an unusual size.

7 But to give you just a general
8 definition, it's kind of a broad topic
9 because it depends on the scope of business
10 of the manufacturer, of the customer, the
11 type of products, the needs, so the -- prior
12 to ever shipping an order, the importance is
13 to understand what the legitimate needs is of
14 a customer.

15 Q. Yesterday you testified that it
16 was important to understand what a usual
17 order was so that you could determine what a
18 suspicious order was.

19 Do you generally recall that
20 testimony?

21 A. I think that's a general
22 description. I think we were discussing the
23 size, so I think before you would know an
24 unusual size, you would need to know the
25 usual size.

1 Q. What does that term mean?

2 MR. FULLER: Form.

3 A. Well, manufacturers are in a
4 unique position at the top of the
5 distribution chain, that their products pass
6 through distributors down to pharmacies.

7 So there's a couple concepts
8 within that know your customer's customer.
9 There's, of course, if you have the
10 information that you already have the ability
11 to know, things like chargebacks and IQVIA,
12 that's an example of information, know
13 your -- you know, you know your customer's
14 customer.

15 Secondly, a manufacturer would
16 have the responsibility under the maintenance
17 of effective controls to do an analysis of
18 who their customers are, which would be the
19 distributors.

20 So it would be incomplete to go
21 do an analysis on them when they don't have
22 an understanding of where their products
23 would ultimately go.

24 BY MR. O'CONNOR:

25 Q. If a manufacturer wanted to

1 understand what this idea of know your
2 customer's customer meant, it couldn't look
3 in the regulations, could it, because it's
4 not there?

5 MR. FULLER: Form.

6 A. I think it's encompassed in the
7 maintenance of effective controls.

8 BY MR. O'CONNOR:

9 Q. But to be clear, the
10 maintenance of effective controls regulation
11 does not mention anything about knowing your
12 customer's customer, does it?

13 A. It doesn't give any specific
14 guidance, but I think what it does is it puts
15 a manufacturer or any registrant on notice
16 that their continued use of a DEA
17 registration requires them to take steps to
18 prevent diversion, and I believe that getting
19 that information is one of those steps.

20 But so just -- just so it --
21 but I guess if your question is does it
22 specifically say that term? It does not.

23 Q. And DEA never issued any
24 guidance to manufacturers informing them of
25 their supposed obligation to monitor -- or to

1 know their customer's customers, correct?

2 MR. FULLER: Form.

3 A. I know I've reviewed where it
4 was presented at some training, but I'm not
5 sure if that was by an industry or a
6 consultant.

7 BY MR. O'CONNOR:

8 Q. DEA --

9 A. So I'll say no.

10 Q. DEA --

11 A. I'm not aware of it. At least
12 I'm not aware they've done it. I'm not
13 saying they have not done it.

14 Q. DEA never published guidance in
15 the Federal Register saying anything about
16 knowing your customer's customer, did it?

17 A. They have not done that.

18 Q. Okay. And they never sent a
19 letter to all manufacturers, for example,
20 saying they were to know their customer's
21 customer, did they?

22 A. I'd like to look at the 2007
23 letter. I think it may say all relevant
24 transaction information, and I would consider
25 that relevant transaction information.

1 prescribed in the MOA can be greater than the
2 duties imposed by statute, fair?

3 A. No, I don't agree with that. I
4 think under maintenance of effective
5 controls, that's a broad regulation, and I
6 think all of these things fit under there.

7 I think I could -- I could hold
8 another manufacturer, if I was still a DEA
9 diversion investigator. I think the
10 statements entered because it kind of affirms
11 that that is a -- to me, that they
12 acknowledge that that is their
13 responsibility, because I wouldn't expect
14 them to do it if they didn't think it was.

15 Q. Just to be clear, are you
16 saying that every duty that's imposed on any
17 registrant through a memorandum of agreement
18 is by definition also required by the law?

19 MR. FULLER: Form.

20 A. Yes.

21 BY MR. O'CONNOR:

22 Q. Are you aware of any DEA
23 guidance that's ever been issued that
24 supports the statement you just made?

25 A. In regards to the -- whether

1 the MOAs are all legal requirements? No,
2 sir.

3 Q. Okay. In connection with your
4 opinion, you examined the suspicious order
5 monitoring programs of seven manufacturers,
6 correct?

7 A. Yes, sir.

8 Q. And each of those programs or
9 systems was different from one another,
10 correct?

11 A. Yes, sir.

12 Q. And you believe they all fell
13 short of the regulatory responsibilities
14 imposed by the CSA and CFR, correct?

15 A. Yes, sir. Just to add the
16 caveat that some of them didn't have systems,
17 but, yes, sir.

18 Q. Fair to say of the seven you
19 saw, you weren't satisfied with any of them?

20 A. That's correct.

21 Q. Have you ever come across a
22 manufacturer's suspicious order monitoring
23 program that you did think satisfied
24 regulatory requirements?

25 MR. FULLER: Form.

1 A. I can think of one.

2 BY MR. O'CONNOR:

3 Q. What was that?

4 A. I'm not sure I can discuss that
5 with the Touhy letter.

6 MR. FULLER: Not if it was
7 based on an investigation that you did
8 while an agent.

9 MR. O'CONNOR: Sorry, are you
10 not answering that question?

11 THE WITNESS: That's what I
12 stated, sir.

13 MR. O'CONNOR: Okay.

14 THE WITNESS: Because it's not
15 publicly readily available that
16 someone would know that.

17 BY MR. O'CONNOR:

18 Q. While we're talking about
19 Touhy, you have said and your counsel has
20 stated on a number of occasions yesterday and
21 today that you're not permitted to speak
22 about any particular investigation you were
23 involved in while at the DEA; is that fair?

24 A. That's not publicly or readily
25 available.

1 Q. Okay. And with respect to
2 Mallinckrodt in particular, given those
3 restrictions, is it fair to say that all of
4 the opinions you express in your report are
5 based on materials that you reviewed in
6 connection with this litigation?

7 A. Yes, sir.

8 Q. And your opinions are not based
9 on any other information outside of what
10 you've relayed and referred to in your
11 report?

12 A. Well, it's difficult to --
13 since I worked the case for a period of
14 years, obviously, that there may be things I
15 know that aren't part of the discovery, but
16 the opinion I wrote is only based on the
17 information contained in my report.

18 Q. Okay. And do you intend at
19 trial to offer any information or opinions
20 that are based on something other than what
21 you've cited here in this report?

22 MR. FULLER: Object to form,
23 based on the same basis earlier.

24 A. If the Touhy letter is in place
25 and it's restricted by the government, then I

REDACTED

3 Q. How much oxycodone would a
4 pharmacy have to purchase for you to conclude
5 that it's diverting oxycodone?

6 A. I'd have to see their customer
7 file and what their scope of business, who
8 they're supplying to be able to make that
9 determination. There's not just a --

10 Q. And that's because you cannot
11 determine whether diversion is occurring
12 simply by looking at the volume, correct?

13 A. That's not correct. So if we
14 look at a pharmacy with a population of 1,000
15 people and there's a million pills go
16 there -- and that's an extreme case, but I
17 think I could clearly say there's something
18 occurring, diversion's occurring there.

19 If it's an amount that's not
20 consumable by that geographic area, I would
21 say it's very likely that there's diversion
22 occurring.

23 Q. Outside of this extreme case
24 that you mention where there's a population
25 of 1,000 getting a million pills, fair to say

1 that a manufacturer can't tell if the
2 diversion is occurring simply by looking at
3 the volume of a purchase?

4 A. Are you saying that if they saw
5 that situation, they would say that diversion
6 is occurring and then outside of that
7 situation? I think generally speaking, just
8 looking at volume of a pharmacy, I think they
9 would have sufficient data.

10 So let's say, for example,
11 Mallinckrodt, they distribute to many
12 distributors who then distribute to many
13 pharmacies, so I think they have established
14 a pretty good baseline of what a usual order
15 is. So I think they would identify some
16 pharmacies by volume that would rise to a
17 level of suspicion.

18 I would agree -- generally
19 agree that in most cases the amount of the
20 drug alone wouldn't immediately make them
21 suspicious -- say that that is a suspicious
22 order, but I think there is a point or a
23 volume where it's very likely that is going
24 to occur. Florida would be an example of
25 that.

1 Q. With respect to your review of
2 manufacturers' suspicious order monitoring
3 programs, what methodology did you apply in
4 coming to your opinions?

5 A. The one that was identified or
6 the lack of one that was identified by each
7 manufacturer.

8 Q. But what methodology did you
9 apply when assessing the suspicious order
10 monitoring programs?

11 A. Well, I would apply my
12 training, experience, knowledge in doing
13 these kinds of cases, in regards to what I --
14 was provided to me to make judgment and form
15 an opinion.

16 Q. And when you say "provided to,"
17 you mean by plaintiffs' counsel?

18 A. No, by -- in discovery.

19 Q. And you received that
20 discovery -- those discovery materials
21 through plaintiffs' counsel, correct?

22 A. Yes, but at my direction of
23 what documents I wanted to see. I know we'll
24 get back to the --

25 Q. So you --

1 A. -- the, you know, whether
2 everything was provided to me, but my opinion
3 is based on -- which I believe is everything
4 that was available and the topics I
5 requested.

6 Q. Okay. So your opinion is based
7 solely on your review of the documents that
8 you received and that -- and your experience;
9 is that fair?

10 A. Experience and training, yes,
11 sir.

12 Q. Okay.

13 A. And legal guidance.

14 Q. From plaintiffs' counsel?

15 A. No, from my employment with the
16 DEA.

17 Q. So your own legal opinions?

18 A. No, receiving legal guidance
19 from lawyers.

20 Q. Okay. At DEA?

21 A. Yes, sir.

22 Q. Okay. Are you familiar with
23 Scott Higham?

24 A. The Washington Post reporter?

25 Q. Yes.

1 A. Yes, sir.

2 Q. Have you ever had a
3 conversation with Scott Higham?

4 A. Yes, sir.

5 Q. How many times?

6 A. I don't know, four or five.

7 Q. What was the substance of those
8 communications?

9 A. Initial were he was writing an
10 article about the DEA and the new -- I think
11 it was a regulation or change in the law --
12 change in regulation or law which was in
13 regards to when a registrant sees some
14 adverse or administrative action, they get to
15 do a correction plan. And I think he wanted
16 me to make some comments on that, so I
17 provided some comments I believe that he
18 published in an article.

19 Q. Did you ever discuss
20 Mallinckrodt with Scott Higham?

21 A. I believe I probably did,
22 postsettlement.

23 Q. When was your first
24 conversation with Mr. Higham?

25 A. I don't recall.

1 investigation, whether you would raise those
2 with the registrant?

3 MR. FULLER: Same objection and
4 instruction. Point out to counsel
5 that we have a 30(b) of the DEA on
6 Friday and you can ask the question.

7 THE WITNESS: I'm not going to
8 answer the question because of the
9 Touhy.

10 BY MS. LUCAS:

11 Q. Well, are you aware that
12 Mr. Prevoznik has testified that if the DEA
13 has concerns about a registrant's suspicious
14 order monitoring written policies, it would
15 raise those concerns with the registrant?

16 A. I would -- I would either not
17 be surprised or not surprised that he raised
18 those concerns, but I believe he would be, in
19 his position, in a better position to be able
20 to know whether to release that information
21 and the public availability. I don't. Or
22 whether he has a Touhy authorization to speak
23 to that or not.

24 Q. Well, you're not telling me
25 that if a DEA diversion inspector came to

1 Janssen and inspected the system, the
2 suspicious order monitoring system, and had
3 concerns about that program, you're not
4 telling me that they would just do nothing,
5 right?

6 MR. FULLER: Object to form.

7 Same Touhy issue.

8 A. I can't answer that because of
9 the Touhy issue but I'm not making a comment
10 one way or the other on that statement.

11 Taking the Touhy doesn't mean
12 that I'm not answering affirmatively or
13 negatively.

14 BY MS. LUCAS:

15 Q. Whether a suspicious order
16 monitoring program is compliant with the CSA
17 depends on the type of company and the scope
18 of the business model and customers you said
19 earlier, correct?

20 A. Some of the things, yes, ma'am.

21 Q. Would it also depend on the
22 medications at issue? Yes or no?

23 A. That could have a bearing also.

24 Q. The abuse rates of those
25 medications?

1 A. Yes, or the nonabuse rates.

2 Q. The geographic location or
3 where they're being sold?

4 A. Yes.

5 Q. The sales volume in that
6 geography?

7 A. That could be another factor,
8 yes, ma'am.

9 Q. All right. I'm going to ask
10 you some quick yes or nos and then I need to
11 pass the witness while reserving my rights
12 since I have many, many more questions for
13 you.

14 Do you know how many customers
15 Janssen had during the time it sold
16 Duragesic?

17 A. No, I do not.

18 Q. Do you know how many customers
19 Janssen had during the time it sold Nucynta?

20 A. I have not evaluated that
21 information as far as the ARCOS, so, no, I do
22 not at this time.

23 Q. Do you know how many orders per
24 month Janssen received from its customers for
25 Duragesic?

1 A. No, I do not at this time.

2 Q. Do you know how many orders per
3 month Janssen received from its customers for
4 Nucynta?

5 A. No, I do not, not at this time.

6 Q. Do you know Janssen's market
7 share for its opioid medications sold in the
8 Track 1 jurisdictions?

9 A. No, I do not at this time.

10 Q. Do you know the rates of
11 diversion for Duragesic or Nucynta in the
12 Track 1 jurisdictions?

13 A. I'm not sure there's any
14 analysis or information available to give any
15 concise rate of diversion of any drug.

16 Q. So is that a no?

17 A. I think that's a no.

18 Q. Do you know how many shipments
19 of Duragesic Janssen flagged through its
20 algorithm and investigated as potentially
21 suspicious?

22 A. Janssen's never reported a
23 suspicious order to the DEA.

24 Q. My question was different.

25 A. Oh, I'm sorry. Misunderstood

1 it then.

2 Q. Do you know how many shipments
3 of Duragesic Janssen's algorithm flagged and
4 Janssen subsequently investigated before
5 releasing?

6 A. I do not.

7 Q. Do you know how many shipments
8 of Nucynta Janssen flagged as potentially
9 suspicious and investigated before releasing?

10 A. I didn't do that type of
11 analysis up to today on that, on the data in
12 regards to those products and that
13 registrant.

14 Q. Yes or no, did you know that
15 Janssen has reported a physician to the DEA
16 based on a sales representative's tip?

17 A. I have not reviewed a document
18 that had indicated that to me, no, ma'am.

19 Q. Do you know of any instance in
20 the Track 1 jurisdictions of Duragesic being
21 diverted?

22 A. At this time, no, ma'am.

23 Q. Do you know of any instance in
24 the Track 1 jurisdictions of Nucynta being
25 diverted?

1 A. At this time, no, ma'am.

2 Q. Do you know how many
3 inspection -- or strike that.

4 Do you know how many regulatory
5 investigations Janssen -- strike that again.

6 Do you know how many DEA
7 regulatory investigations of Janssen
8 distribution centers were conducted during
9 the relevant time period in this case?

10 A. I do not because that
11 information would not be available to me.

12 Q. Are you aware, yes or no, that
13 the DEA conducted multiple regulatory
14 investigations of Janssen using at least 14
15 different DEA diversion investigators since
16 2008?

17 A. Were those regulatory
18 investigations that -- I'm sorry, with your
19 question --

20 Q. Were you aware of --

21 A. Could you answer --

22 Q. Well, let me --

23 A. Could you restate that for me?
24 Just whether it was inspections or regulatory
25 investigations, I just need clarification.

1 Q. Were you aware that the DEA
2 conducted multiple regulatory investigations
3 of Janssen using at least 14 different DEA
4 diversion investigators since 2008?

5 A. No, I'm not aware of that, but
6 just for clarification purposes, I've been at
7 manufacturers where there were groups of
8 people, so the number, multiple, I would
9 acknowledge is more than one.

10 But when you say 14 people, to
11 go to a manufacturer, sometimes there are
12 large groups of people that go, so...

13 Q. Is that a no?

14 A. It's -- so I would answer that
15 with the information you provided me, I
16 wouldn't comment. I don't know one way or
17 the other.

18 Q. Were you aware of any
19 regulatory investigations of Janssen by the
20 DEA since 2008?

21 A. I don't have any direct
22 knowledge of any investigations, ma'am.

23 Q. Did you ask to see any
24 documents reflecting DEA regulatory
25 investigations of Janssen?

1 A. I believe he did make that
2 comment, yes. He didn't say that it was
3 sufficient to be compliant, but he did say it
4 was an improvement.

5 Q. But again, he didn't say that
6 it wasn't compliant with DEA regulations?

7 A. No, I didn't say that.

8 Q. My question to you is: He
9 didn't say that it wasn't compliant with DEA
10 regulations?

11 A. He never made that exact
12 statement.

13 Q. Teva also had an internal audit
14 of its own suspicious order monitoring
15 program?

16 A. I believe so, yes.

17 Q. And that program was rated
18 overall as effective, correct?

19 A. Yes, but it's an internal
20 audit.

21 Q. The DEA regulations don't
22 require that companies actively audit their
23 own programs, correct?

24 A. No, that's true. But I only
25 make that statement because sometimes the

1 person that does the audit, without knowing
2 the full information on the audit, is the
3 person in charge of the system, so they don't
4 typically give a bad audit to themselves.

5 So, I mean, I'm not totally
6 discounting it, but I'm always concerned
7 about internal audits.

8 Q. Mr. Rafalski, in your report
9 you don't identify any suspicious order that
10 Teva shipped to Summit County or Cuyahoga;
11 isn't that correct?

12 A. I do not identify any single
13 suspicious order -- any order specifically
14 that was suspicious.

15 Q. And that goes for Cephalon and
16 the Actavis entities as well, correct?

17 A. As I sit here today, that's an
18 accurate statement.

19 Q. And you don't identify any
20 order that Teva failed to flag as suspicious?

21 A. Is that question a specific
22 order?

23 Q. Any order that Teva failed to
24 flag as suspicious, you don't have an example
25 of any specific order?

1 A. No, I think my examples in here
2 are more -- go more to the conduct of the due
3 diligence and it doesn't specifically say
4 that there was a specific order, but I think
5 the totality of the incident that I describe
6 on page 183 I think would include that, but
7 to answer your question, there's no specific
8 order where I state that.

9 Q. And I want to ask you quickly
10 about that order.

11 You're speaking of the Publix
12 Supermarket pharmacies incident or scenario
13 that we discussed -- that's in your report on
14 page 183?

15 A. Yes, I am.

16 Q. The orders involving the Publix
17 Supermarket pharmacies were not orders placed
18 from Publix to Teva, were they?

19 A. No, they were placed to a
20 distributor, an in-between so --

21 Q. Right. They were orders placed
22 from Publix to Anda, correct?

23 A. Yes. But so the first concern
24 that I would have with this is that Teva
25 would need a means of effective controls to

1 go to Anda and see why this situation
2 occurred.

3 Q. And it did do that, correct?

4 A. I don't recall that occurring.

5 Q. Well, so you read the
6 deposition of Joe Tomkiewicz, didn't you?

7 A. Yes.

8 Q. And sitting here today, you
9 don't know whether any of Teva's product was
10 ultimately shipped to one of those Publix
11 Supermarkets that Joe Tomkiewicz identified
12 as entities he wanted to look into, correct?

13 A. Based on my review, he was
14 looking at the chargebacks, and I believe
15 they were Teva products.

16 Q. But you would agree with me
17 that Joe Tomkiewicz testified he didn't see
18 any specific orders of Teva's products,
19 correct?

20 A. Yes, but if they weren't Teva's
21 products, I'm not sure that he would have
22 taken all this action unless he was
23 indicating it was someone else's product that
24 he was going to go investigate.

25 Q. Well, he could have been

1 Q. And so I'd like you, if you
2 could, to just open your report to page 7.
3 You know that Anda, Inc. is one of the
4 defendants in this action, right?

5 A. I believe so, yes, sir.

6 Q. Okay. Looking at page 7 of
7 your report, in the second full paragraph,
8 you wrote: I am of the opinion to a
9 reasonable degree of professional certainty
10 that there was a systematic, prolonged
11 failure over many years by the defendant
12 manufacturers and distributors to maintain
13 effective controls against diversion of
14 legitimate opioid prescriptions into the
15 illicit market.

16 Did I read that correctly?

17 A. You did.

18 Q. So Anda is a defendant, right?

19 A. Yes, sir.

20 Q. And that opinion as described
21 on page 7 does not apply to Anda, right?

22 A. As I sit here today, no, I have
23 not reviewed any records related to Anda.

24 Q. Okay. I want to ask one more
25 question following up on your testimony.

1 During the course of the
2 deposition, you've said on several occasions
3 that your method for assessing the
4 defendants' suspicious order monitoring
5 systems is based in part on your experience,
6 training and guidance from lawyers at DEA; is
7 that correct?

8 Do you remember that testimony?

9 A. Yes, sir.

10 Q. Okay. This is just a yes-or-no
11 answer: Does the Touhy authorization that
12 you received for today's testimony prevent
13 you from disclosing the legal guidance from
14 DEA lawyers that supports your opinions?

15 A. So just so I understand the
16 question. Does the Touhy letter prevent me
17 from answering that question?

18 Q. Right.

19 A. I believe it does, yes.

20 MR. MATTHEWS: Thank you. I
21 have no further questions.

22 THE VIDEOGRAPHER: Going off
23 the record, 5:18 p.m.

24 (Proceedings recessed at
25 5:18 p.m.)